



Partnering for Pre-IND Success: A Case Study in Regulatory Meeting Strategy

CHALLENGE

An early-stage drug development team for an emerging new company has strong bench strength with a team of biologists and chemists. This is due to the expertise needed to understand a novel mechanism of action and to produce a drug candidate with the optimal characteristics to overcome challenges relative to competitors. These companies have a leadership team with some combination of CEO, COO, CSO, CDO, CMO, CFO, Legal Counsel, and CBO.

Generally, these teams have limited experience with navigating early regulatory interactions with the FDA.

Challenges to overcome included:

- Formulation of a meeting strategy to align topics to request FDA feedback
- Supplementing the team with Regulatory expertise and tactical support where it was not previously available
- Regulatory writing towards preparation of the meeting package and request
- Clinical development planning towards a Phase 1 trial design and development of a draft protocol synopsis
- Coaching and preparation towards a FDA meeting interaction
- Representation at the FDA meeting

Halloran, a PLG company, was requested to provide regulatory leadership, regulatory project management, clinical development, medical writing, and publishing support towards a Pre-IND meeting interaction with the FDA.

CASE STUDY



Situation

A small startup biotechnology company has just nominated their development candidate and is feverishly working towards submitting an Investigational New Drug (IND) application to begin clinical trials. The company wants to de-risk its IND-enabling activities and clinical trial design by holding a Pre-IND meeting with the FDA. Not only will this interaction de-risk continued development, but it will also document the viable path forward for this company and bolster confidence from the board of directors and Venture Capitalists for future funding.

SOLUTION

Halloran employs the following regulatory and clinical strategies to advance its drug development program and help reach the value inflection point to secure additional funding.



GAP ANALYSIS: Finding issues early to de-risk the interaction



SETTING THE MEETING STRATEGY: Developing Ways for positive outcome & interaction



MEETING REQUEST & PACKAGE PREP: Strategizing on content with supportive data



FDA MEETING PREP: Mastering communications and etiquette to achieve results

Gap Analysis

We conducted a comprehensive review of nonclinical and Chemistry, Manufacturing, and Controls (CMC) materials in accordance with FDA guidance to identify regulatory gaps and mitigate risks associated with FDA interactions. Regulatory recommendations were provided to facilitate a successful Pre-Investigational New Drug (Pre-IND) meeting, including guidance on meeting package content and supporting rationale. Additionally, we assessed the current clinical landscape to inform the development of a clinical synopsis and protocol design intended to initiate a Phase 1 clinical study acceptable to the Agency with minimal modifications.

Set the Meeting Strategy

We delivered a high-level overview of regulatory strategy, timelines, and submission processes to ensure team alignment with project objectives. Our experts identified areas requiring risk mitigation and assisted in formulating questions and sponsor positions for presentation to the FDA to optimize meeting outcomes.

Prepare Meeting Request / Package

Our team applied regulatory project management methodologies to establish achievable timelines and coordinate communications and workflows. We supplied document templates and medical writing support, ensured consistency in key definitions and messaging across meeting documents, and conducted regulatory reviews to confirm compliance and relevance. The draft clinical synopsis for the Phase 1 trial addressed trial design, patient eligibility criteria, patient monitoring, endpoints, and statistical methods. Publishing support was provided for submission to the FDA via the Electronic Submissions Gateway (ESG).

FDA Meeting Preparation and Representation

We acted as the primary regulatory point of contact with the FDA on behalf of the company, translating FDA comments into actionable summaries and determining when clarification was necessary. Our team provided coaching to the cross-functional team on meeting etiquette, anticipated questions, preliminary responses, and conducted rehearsals prior to the FDA meeting. We facilitated brainstorming sessions regarding potential FDA feedback and, upon receipt of preliminary feedback, reviewed the meeting agenda and speaking points, and worked with the team to develop responses. We led the FDA meeting on behalf of the Sponsor, documented meeting minutes, and submitted them to FDA.

RESULTS

→ Halloran's regulatory strategy, project management, medical writing, regulatory operations, and clinical expertise enabled an early-stage client to navigate a successful Pre-IND meeting and de-risk development, moving to the next value inflexion point of an IND submission. The sponsor walked away with an FDA-vetted map towards an IND.

Next Steps

Halloran will continue to support a sponsor as they progress through IND-enabling activities by offering regulatory expertise, CMC regulatory expertise, clinical development and operations expertise, and project management. The next inflection point on the horizon is the IND submission that Halloran will be prepared to support.

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