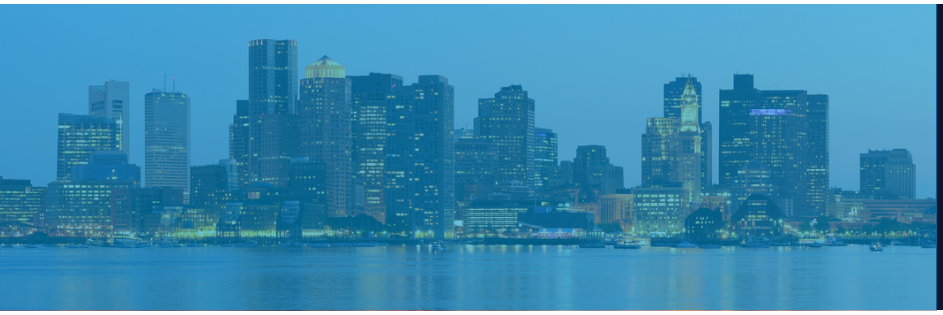
Halloran
CONSULTING GROUP



CASE STUDY:

A SUCCESSFUL PRE-IND ENABLING NEXT STAGE OF DEVELOPMENT

BACKGROUND

Asset: small molecule, oncology
Indication: treatment of advanced and/or malignant solid tumors in non-small cell lung cancer (NSCLC), colorectal cancer, gastric
Regulatory Division: Center for Drug Evaluation and Research (CDER), Division of Oncology 3 (DO3)

SITUATION

A small research and development precision medicine biotech company, with no currently approved products, is bringing their first asset, backed by strong pre-clinical data, through the IND-enabling stage.

The company's team members had little collective previous experience engaging with the U.S. Food and Drug Administration (FDA). They required regulatory expertise to ensure a positive and successful FDA interaction to get to the next stage of development without incurring added costs and time in the overall development program while developing a strong partnership with the FDA.

CHALLENGE

When faced with such pressures, the company approached Halloran Consulting Group (Halloran) and requested regulatory consulting to assess gaps in their current program development, extend leadership and technical expertise in their application review, and provide coaching for FDA communication and interaction.

SOLUTION

The company chose Halloran as their partner because of Halloran's deeply rooted experience with FDA meetings and ability to aggregate data into a succinct Pre-IND meeting request and meeting package, thereby ensuring meaningful FDA feedback.

Halloran offered a full-suite approach from start to finish so the company could reach its next milestone with confidence. Halloran engaged with company leadership, attended in-depth development meetings, and provided directional leadership and technical expertise to their Pre-IND meeting request and meeting package. In addition, Halloran coached the company to prepare for FDA communication and assessments and submitted the Pre-IND document on behalf of the company.

RESULTS

Based on Halloran's leadership and the confidence of the company in their Pre-IND preparation, the Pre-IND documentation was submitted according to the company's specified timeline. The FDA feedback was received well in advance of the initially communicated timeline, which allowed faster decision making for the next stages of development. Strategic positioning of key questions to the FDA resulted in focused, meaningful feedback for the development program. Overall, the FDA gave valuable advice regarding the development program which is now allowing the company to march towards an IND submission.

AFTER A SUCCESSFUL FIRST ENGAGEMENT WITH THE FDA, THE COMPANY WILL BE SUBMITTING THEIR IND TO REACH THEIR NEXT DEVELOPMENT MILESTONE WITHOUT DELAYS OR ADDED COSTS IN THEIR DEVELOPMENT PROGRAM. FDA CONCURRENCE REGARDING THE PROGRAM GIVES THE COMPANY CONFIDENCE IN THE SUCCESS OF THE PENDING IND.

ABOUT HALLORAN

Halloran is a life science consulting firm that provides strategic regulatory, quality, clinical, and organizational support to industry leaders and startup visionaries in the pharmaceutical, biotechnology, and medical device sectors. Halloran experts offer deep expertise in science and advanced knowledge of the development and commercialization lifecycle, leading clients through their most challenging goals to achieve their greatest chance of success.

Halloran's regulatory services span every stage of development, from the preparation of early regulatory strategies for preclinical interactions to commercial and post-marketing activities.

Halloran led or supported approximately 30-35 formal FDA meetings in 2022.

HEALTH AUTHORITY MEETINGS & INTERACTIONS

Halloran acts as its clients' executive regulatory representative at health authority meetings and coaches their clients through their regulatory communication strategy. Halloran proactively assesses the optimal time their clients need to positively engage health authorities, identifies the critical questions and plans to obtain occurrence to move forward and develop meeting requests, and strategically positions briefing documents. Halloran leads teams through practice sessions and pre-meeting coaching to prepare for communication with health authorities.

READY TO GET TO WORK?
CONTACT US.