Leverage Our Regulatory Experts for Pre-IND and IND Support

An Investigational New Drug (IND) application is considered a request from a drug sponsor to obtain authorization from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans. A pre-IND meeting is an opportunity to gain valuable feedback on early product development and design input on the first-in-human (FIH) study from the FDA prior to the IND application submission.

Some of the advantages of a holding a pre-IND meeting include:

- ✓ Avoid premature IND submission and possible clinical holds
- ✓ Avoid unnecessary nonclinical studies
- ✓ Resolve potential safety issues
- ✓ Discuss contents of IND and early drug development plans
- ✓ Obtain regulatory guidance and answers to chemistry, manufacturing and controls (CMC), nonclinical, and clinical development questions

Celerion Differentiators:

Experience:

– Supported over 100 IND applications since 2010

Expertise:

– Expert team with more than 30 years combined clinical research experience

Efficiencies:

– Full service regulatory, scientific and operational support

The ideal period to request this meeting is approximately 3-6 months prior to IND submission, and anticipate about 3-6 weeks to prepare the pre-IND meeting briefing package. Leveraging regulatory experts to prepare the meeting request and briefing package ensures the request meets the FDA's expectations and includes all necessary supportive information. For example, the briefing package should contain (at minimum):

1) CMC data for drug substance and drug product
2) Summary of nonclinical data including topline toxicology results and future plans for additional studies
3) FIH protocol synopsis including inclusion/exclusion criteria and time and events schedule

Prior to or in parallel with preparation for the pre-IND meeting and initial IND filing Celerion can conduct a gap analysis; this step can often be useful for drug developers that initiated a FIH study outside of the US and plan on bringing their program to the US FDA. A multidisciplinary team of regulatory, clinical pharmacology and CMC experts reviews all available sponsor data and associated literature to identify potential deficiencies in the prospective IND package as well as suggest potential solutions to strengthen the application. A gap analysis may also be helpful when preparing for an End of Phase 2 meeting or New Drug Application (NDA) submission.

Preparing for an initial IND filing can be a complex, time-consuming, and labor-intense endeavor. Utilizing regulatory experts, with proven IND management experience, to oversee the authorship, compilation, and submission process will help to ensure an efficient and seamless IND submission. Some benefits of utilizing Celerion's regulatory expertise for IND filing include:

– eCTD compliant template documents
– Module 2 and Module 3 section authorship capabilities
– Document life cycle management and publishing capabilities
– Submission through FDA's electronic submission gateway (ESG)
– Network of pharmacology, toxicology, CMC, clinical, and regulatory specialists/consultants
– Ability to serve as US Regulatory Agent and FDA liaison services

Regulatory Affairs Services

Celerion offers full regulatory and scientific affair services to support every stage of drug development:

Pre-IND Support	IND Support	NDA Support
• Preparation and submission of pre-IND meeting request and briefing package • Investigational Brochure (IB) authorship • Gap analysis • Protocol synopsis and full protocol writing • Drug development program consulting	• IND authorship, compilation, and submission • US agent and FDA liaison services • IND Annual Reports (DSUR) • IB annual updates • IND maintenance (protocol amendments, information amendments, safety reporting) • FDA meeting request and briefing package • FDA expedited program request ✓ Orphan drug designation ✓ Fast track ✓ Breakthrough therapy ✓ Accelerated approval ✓ Priority review	• NDA authorship, compilation, and submission • Prescribing information authorship (USPI, IFU, PPI) • Preparation and submission of pre-NDA meeting request and briefing package • Authorship of initial pediatric study plans and pediatric study waiver requests