# The Basics of a Pre-IND Meeting

Meetings with regulatory boards provide guidance to researchers who seek to comply with regulatory requirements and ease the drug approval process.

**BY ARON SHAPIRO**

The pathway to an approved drug involves a long, expensive journey through basic research, preclinical development, clinical trials, and regulatory approval. Before sponsors invest significant amounts of time and money developing a product, it is important that they seek input from the regulatory agency that will approve their drug. Doing so will guide preclinical and clinical strategies and cultivate a target product profile early in the development process, which increases the probability of a successful development program and decreases the likelihood of encountering costly delays. Within this context, of particular concern is clarity regarding the Investigational New Drug (IND) process. Understanding the logistics of a pre-IND meeting with the US Food and Drug Administration (FDA) can facilitate a sponsor's pathway to approval. This article will describe how sponsors can derive maximum benefit from engaging the FDA to help guide the development process. (Note: This article focuses on drug development as an example, but a similar process, called a pre-submission program, is applicable to development of a device.)

## PRE-IND MEETING

Sponsors looking for pre-IND guidance must request a Type B meeting with the FDA, which can be an opportunity to build a relationship with the FDA and gain valuable feedback on any questions regarding drug development. Although the FDA does not require these meetings, they are recommended because such meetings can confirm the requirements of the development process. It may be advantageous to meet with the FDA early in the drug development process so that any recommendations and answers to questions can be integrated into the development program. These meetings are most effective when they are focused on specific scientific or regulatory issues, such as clinical trial design, pharmacology studies, toxicology studies, acceptability of novel formulations, dosing limitations, data requirements for an IND application, and regulatory requirements for demonstrating safety and efficacy to support a new drug approval.

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## REQUESTING A PRE-IND MEETING

In order to request a pre-IND meeting, sponsors must submit a formal letter to the responsible project management staff or other designated personnel of the Division of Transplant and Ophthalmology Products.[1] In order for the request to be as complete as possible and to give the FDA an accurate understanding of what the sponsor hopes to obtain from the meeting, the meeting request should contain the following elements:[1]

- product name;
- application number;
- chemical name/structure;
- proposed indication or context of product development;
- type of meeting being requested (pre-IND meetings are Type B meetings);
- purpose and objectives, including background, summary of studies completed, clinical study plan, and the nature of questions to be asked;
- proposed agenda;
- list of questions, grouped by discipline (eg, chemistry, manufacturing, and controls; clinical; biostatistics; pharmacology/toxicology; etc.);
- list of individuals, titles, and affiliations of those who will attend the meeting on behalf of the sponsor;
- list of FDA staff or disciplines asked to participate in the meeting (optional);

- suggested dates and times (morning or afternoon) for meeting (eg, no later than June 15, 2014, or no earlier than December 1, 2014); and
- format of the meeting (face-to-face, teleconference, videoconference, etc.).

The teleconference is a popular meeting format because they are easier to schedule and manage and are less costly than face-to-face meetings. Speculative and open-ended questions are difficult to address; meetings are typically most productive when questions are focused and specific. Questions for the FDA should be posed in such a way that the agency can either agree or disagree with the question. Here are some sample questions:

- Does the agency agree that no additional toxicology testing is required to support the proposed clinical study?
- Does the agency agree that the proposed clinical study design, including the primary endpoint, visit schedule, study procedures, and inclusion/exclusion criteria, are acceptable?
- Does the agency agree with the proposed statistical analysis plan?

The timing of the pre-IND meeting often depends on the complexity of the discussion topics. Sponsors that prefer to obtain confirmation of toxicology plans and manufacturing will benefit from a meeting held 6 months to 1 year prior to the planned IND submission. In such cases, a meeting request should be submitted approximately 60 days prior to the desired meeting date.

**There are 3 types of formal meetings that occur between the FDA and sponsors.[1]**

1. Type A meetings are held to help move along a stalled development program. Reasons for stalled programs might include dispute resolutions, issues with the program that have put the clinical program on hold, or follow-up on special reviews of a clinical study design (called special protocol assessments).
2. Type B meetings include pre-IND, certain end-of-phase 1, end-of-phase 2 and 3, and pre-New Drug Application and Biologics License Application meetings.
3. Type C meetings are any other meeting between the agency and a sponsor regarding the development and review of a product.

The FDA will respond to a request for a pre-IND meeting within 21 days of receiving the request.[1]

## PRE-IND BRIEFING PACKAGE

If the FDA meeting is granted, sponsors must provide a pre-IND meeting briefing package to the Division of Transplant and Ophthalmology Products at least 4 weeks prior to the meeting.[1] Meeting packages are much more detailed than meeting request letters and should provide summary information relevant to the product, organized according to the proposed agenda. If the intent of the meeting is to discuss clinical requirements of the pre-IND package, the sponsor should submit a proposed clinical trial protocol and statistical analysis plan, to which the FDA will respond after a review. The principal aim of the pre-IND meeting is to ensure that the drug development plan and future clinical trials are going to be acceptable to the FDA. This is an opportunity for sponsors to gain valuable feedback from leaders in the industry. It is important that sponsors remember that maximum transparency with intended clinical plans leads to maximum meeting value.

## OTHER FORMAL MEETINGS

In addition to pre-IND meetings, the FDA offers other opportunities to formally engage for guidance on development programs.[1] Type A meetings are held to help move along a stalled development program. Reasons for stalled programs might include dispute resolutions, issues with the program that have put the clinical program on hold, or special reviews of a clinical study design (called special protocol assessments). Type C meetings are any other meeting between the FDA and a sponsor regarding the development of a product.

## CONCLUSION

Building a strong relationship with the FDA is essential for a successful drug program. This begins with taking advantage of the valuable information that can be gleaned from pre-IND meetings. Proper utilization of pre-IND meetings may reduce the drug's time to market and ensure that the proposed studies are designed to provide useful information. Sponsors who are forthcoming with potential issues of concern during the drug development process will benefit from input provided by the regulatory agency. ■

*Aron Shapiro is vice president of retina at Ora in Andover, Massachusetts.*

1. Guidance for Industry: Formal Meetings Between the FDA and Sponsors or Applicants. US Food and Drug Administration website. http://www.fda.gov/downloads/Drugs/Guidances/ucm153222.pdf. Accessed June 18, 2014.