Is An FDA Pre-IND Meeting Worth It? How To Decide & How To Prepare

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This is the first in a three-part series on planning for a successful investigational new drug (IND) application.

If you are considering whether to take the time in advance of your investigational new drug (IND) application submission to meet with FDA for feedback on your development program, here are some thoughts to ponder and reasons not to pass up this valuable opportunity.

The pre-IND meeting represents a critical point in the regulatory process and remains one of the near-guaranteed opportunities to obtain valuable FDA feedback, while establishing a strong relationship with the agency. Though it requires a couple of months from the time you submit a meeting request to the time feedback is obtained, the pre-IND meeting has the potential to save time in the long run and can really shape the overall strategy for drug development for the compound under study.

If you’re wondering how adding a pre-IND meeting could possibly reduce time to market, you’re not alone. The FDA has actually addressed this question on their website, indicating that time can be reduced by the following:

- Identifying and avoiding unnecessary studies
- Ensuring that necessary studies are designed to provide useful information
- Gaining FDA support for a proposed strategy
- Potentially minimizing potential for clinical hold
- Providing opportunity for creative exchange of ideas
- Obtaining regulatory insight
- Minimizing costs
Clearly defining endpoints and goals of the development program
Allowing early interactions/negotiations with FDA

As mentioned, the pre-IND feedback can help identify studies to support the initiation of clinical trials and can provide insight as to whether development can be enhanced by methods/programs such as orphan drug designation, fast track designation, accelerated approval, Animal Efficacy Rule, or even breakthrough therapy designation.

**Determining If A Pre-IND Meeting Is Right For Your Product**

Take a moment now to think about your product: Is it intended to treat a serious or life-threatening condition? Is there a novel indication being considered? Are there no current guidance documents available? Are there pharmacologic and/or toxicologic signals of concern? Is the drug a new molecular entity?

If you answered “yes” to one or more of these questions, then you should give serious consideration to engaging FDA prior to submitting the IND.

Still not convinced?

There is no cost associated with the pre-IND meeting, and there is even a new option to request written feedback instead of taking your team to Maryland for a face-to-face interaction, sparing you the associated costs for travel, on-site meeting prep, etc. Videoconferences and teleconferences are also available meeting format options. Please keep in mind, though, that the agency will determine the format of the meeting depending on available resources and the types of questions the sponsor wishes to discuss.

Although there is planning (and time) involved in the creation of the formal meeting request for a pre-IND meeting, this early interaction with FDA can provide information to help ensure that you submit a complete IND application and potentially avoid clinical hold issues. If you’re a small company that has had limited experience interacting with FDA or are unfamiliar with pre-IND meetings, this opportunity to ask questions and receive feedback may be especially helpful.

**Requesting A Pre-IND Meeting**

So, you’ve decided that a pre-IND meeting would be a good idea. Wise choice. Now, what? Well, there are three types of formal meetings that sponsors can request with FDA: Type A, Type B, and Type C. Each meeting type is subject to different timelines and procedures. A pre-IND meeting is considered a Type B meeting, which are usually scheduled within 60 days of a written request. So, for planning purposes, you should plan to submit your pre-IND meeting request approximately two months before you would like to have your meeting with FDA.

Next, you will need to make a written request. Your request should include the following 13 items:
Preparing For The Meeting

Keep in mind that a well-written meeting request that uses the above components as a guide can help FDA understand and assess the utility and timing for the meeting related to product development.

Once FDA receives your formal meeting request, they will determine whether to grant the meeting and will respond with a meeting granted or denied notification within 21 days of receipt of the meeting request. In this same timeframe, FDA will also indicate the date that they intend to provide written feedback, if that is the meeting format requested or deemed most appropriate by the agency.

Generally speaking, FDA will grant most pre-IND meetings, but keep in mind that this is really your one shot on goal, as you can only have one pre-IND meeting per application (e.g., IND, new drug application (NDA), biologics license application (BLA)).
Your pre-IND meeting has been granted! What’s up next on the to-do list? You must submit your briefing document to FDA at least one month before the scheduled meeting date (or date of expected receipt of written feedback).

In short, the briefing document should provide summary information relevant to the product and any supplementary information needed to develop responses to potential issues raised by you (as the sponsor) or FDA. Though the briefing document content will vary depending on the product, indication, phase of product development, and issues to be discussed, it is critical that the entire briefing document content supports the intended meeting objectives.

Your briefing document has been submitted to FDA – check! Your meeting date (assuming no written feedback) should now be about a month away. Time to sit and twiddle your thumbs? Hardly. Now comes one of the most important aspects of a pre-IND meeting (or any face-to-face interaction with FDA): meeting preparation and rehearsal.

Although formal presentations by sponsors are generally unnecessary, the meeting attendees (especially those with anticipated speaking roles based on the questions) need to ensure that they know the information in the briefing document inside and out. The team heading to the meeting with FDA should be well-versed on the program as a whole, the data to be discussed, and any potential issues the sponsor is aware of or that the sponsor expects FDA may hone in on.

Contingency plans should also be discussed and agreed upon in advance of the meeting. In the event that FDA doesn’t quite like something that is being proposed, you will have the ability to suggest and perhaps obtain feedback. It may even be appropriate to stage a mock FDA panel and ask other team members to play the role of FDA, putting attendees on the spot so they are comfortable in the hot seat.

Roughly two to three days in advance of your scheduled meeting, FDA will typically send preliminary meeting feedback, following internal meetings they have held to discuss your briefing document and gain alignment on preliminary responses to your questions. This pre-meeting communication can serve as a foundation for discussion or as the final meeting responses if the feedback is crystal clear and you wish to cancel the meeting altogether. (Yes, you do have that option.)

If the meeting goes ahead as planned, it will be chaired by an FDA staff member and will begin with introductions and an overview of the agenda. The meeting will then focus on the questions you wish to discuss. Often, the preliminary feedback is very detailed and informative, and you can spend the allocated meeting time discussing one or two questions you would like to have clarified. Before the end of the meeting, FDA and sponsor attendees should summarize the important discussion points, agreements, clarifications, and action items. It is critical to ensure this information is preserved for future reference. This can be done while minutes are being typed live onto a projected screen by a member of FDA staff. FDA intends to issue the official, finalized minutes to the requester within 30 days of the meeting.
What’s Next?

So now that you’ve reached the important milestone of obtaining pre-IND feedback, what do you do next? Most likely, with this feedback in hand, your team will move towards the next step in development: submitting the IND. Stay tuned for part 2 of this three-part series for information on planning for and submitting an IND to FDA.

For more on the specific requirements of a pre-IND meeting, you can refer to 21 CFR 312.82 and also review the FDA Draft guidance *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products.*

About The Authors:

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