

Pre-IND Meeting

This meeting is conducted at the early stage in the drug development process. The sponsor requests this meeting in order to discuss with the FDA about testing and data requirements, and any scientific issues that may need to be resolved before IND submission. The purpose of the meeting varies with each product and could include discussion of nonclinical safety study issues; chemistry, Manufacturing, and Control (CMC) issues; clinical trial design issues related to the investigational drug; or identification of potential clinical hold issues. This meeting is not required by the FDA, but is highly recommended in order to expedite the drug development process. The timing of the Pre-IND meeting is dependent on the complexity of the issues up for discussion and is often held six months to a year prior to the planned submission.

The sponsor prepares the pre-IND meeting request letter and sends it to the FDA to obtain a date and time for the pre-IND meeting. The letter contains a brief overview of the purpose of the meeting. The letter should include adequate information for the FDA to determine if the meeting is necessary and to identify appropriate participants. The letter should include the following information:

- Product name and IND application number (if applicable)
- Chemical name and structure
- The type of meeting requested (Type B – Pre-IND)
- A brief statement of the purpose of the meeting.
- A list of the specific objectives expected from the meeting
- A proposed agenda, including estimated time for each item and designated speaker(s).
- A draft list of specific questions, grouped by CMC, Nonclinical, and Clinical
- A list of individuals who will be attending the proposed meeting from the sponsor's organization
- A list of FDA personnel or disciplines requested to be present at the meeting
- Estimated date on which the Pre-IND meeting package will be submitted to FDA
- A list of suggested dates and meeting times. The FDA generally schedules Type B meeting to occur within 60-90 days from receipt of written request.

The FDA will respond to a request for a pre-IND meeting with 14 days of receipt of the meeting request letter. The sponsor will receive the response in the form of a letter from the FDA confirming the meeting details.

The following site provides more information about the Pre-IND process:

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/Overview/ucm077546.htm>