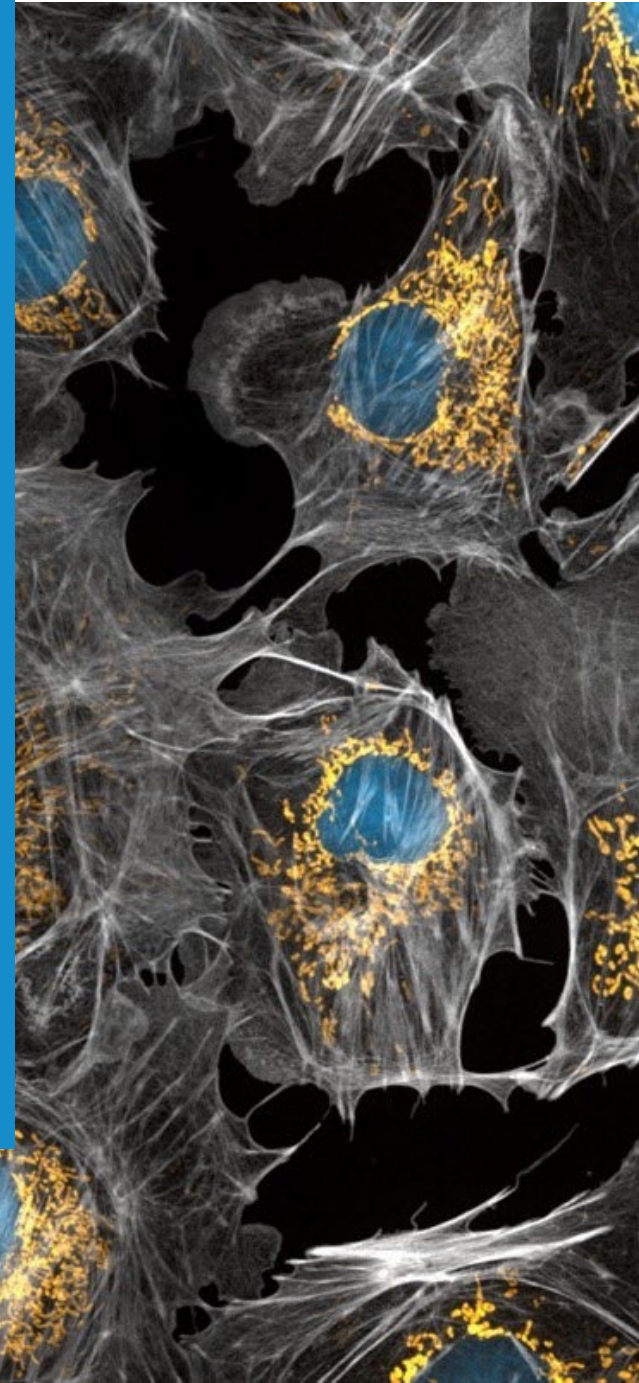


# Pre-IND FDA Meeting General Information

Regulatory Support  
Office of Ethics and Compliance



# The Pre-IND Meeting

- The pre-IND meeting is a formal meeting with the FDA defined in the Code of Federal Regulations ([21 CFR 312.82](#)):
  - “*Pre-investigational new drug (IND) meetings*: Prior to the submission of the initial IND, the sponsor may request a meeting with FDA-reviewing officials. Depending on the stage of drug development, this meeting can be used to review and reach an agreement on the design of animal studies needed to initiate human testing. The meeting may also provide an opportunity for discussing the scope and design of phase 1 testing, plans for studying the drug product in pediatric populations, and the best approach for presentation and formatting of data in the IND.:
- During the meeting, Chemistry Manufacturing and Controls (CMC), *Non-clinical plans*, and initial *Clinical plan* are presented to the Agency (with scientific justification for any nonstandard aspect) for guidance

# The Pre-IND Meeting (cont.)

- The pre-IND meeting is highly recommended in the drug development process, especially if a sponsor-investigator's questions are not fully answered by guidance documents and other information provided by FDA.
- The use of the pre-IND meeting is an invaluable tool in designing the *Chemistry, Manufacturing and Controls (CMC)*, *Non-clinical* and *Clinical* approach being used in support of an IND and later an investigational new drug application (NDA), if applicable.
- Responses to questions are based on the best judgment of the FDA relative to current industry practices and knowledge base at the time of the meeting.
- **Note:** Feedback provided in the FDA meeting is **not** “binding,” and the FDA could change its opinion of what should be done if relevant new information is available before submission of the IND.

# Type B Meetings

- The Pre-IND meeting with the FDA is considered a Type B meeting
- A Type B meeting should be scheduled by the appropriate FDA Division (CDER/CBER) to occur within 60 days of FDA receipt of the written meeting request.
- Meeting Requests should be done through the [FDA NextGen Portal](#). Please remember to obtain a Pre-assignment Submission number (which becomes the IND number) through the NextGen Portal prior to submitting the Meeting Request.
- The meeting can be either a face-to-face meeting, a teleconference, or a written response. Alternatively, the meeting can be denied.
  - If a meeting request is denied, notification to the sponsor-investigator or applicant will include an explanation of the reason for the denial.
  - It is critical that the questions are developed to be specific and well phrased so that clear concise feedback can be provided.
- A briefing document (also called a pre-IND Briefing Packet) with more information to support FDA's understanding of the *Nonclinical*, *CMC*, and *Clinical* program should be provided 30 days before the meeting date agreed with the FDA.

# Pre-IND Meeting Request Content

1. Meeting objective
2. Proposed agenda, including estimated times needed for each agenda item
3. Listing of specific questions categorized and grouped by discipline, for example, CMC, pharmacology/toxicology, clinical pharmacology and biopharmaceutics, and clinical investigations
4. List of sponsor participants
5. List of requested participants from FDA
6. Quantitative composition (all ingredients by percent composition) of the drug proposed for use in the study to be discussed
7. Proposed indication
8. Dosing regimen, including concentration, amount dosed, and frequency and duration of dosing if known
9. Proposed meeting date (propose 6-8 weeks in the future)
10. When the briefing document will be available (at least 4 weeks before the proposed meeting date)

# Pre-IND Briefing Packet Content

1. Overall program synopsis
2. Whether the animal efficacy rule is being considered
3. Clinical study synopsis to obtain FDA input on inclusion, exclusion, and endpoints
4. Results for *in vitro* and early *in vivo* toxicology
5. Rationale for safety, based on toxicological profile and safety margin using dose regimen and exposure
6. Brief description of the manufacturing scheme for the active pharmaceutical ingredient (API) and formulation for clinical study
7. Brief assay descriptions
8. Full description of the development plan
9. Copy of the meeting request with updates to reflect the most current information

# Before the Meeting

- Approximately 24 hours before the meeting is scheduled to occur, the FDA will send draft responses to the questions in the Meeting Request.
- The Sponsor-investigator should review the questions with the entire development team and decide if the FDA responses are clear and agreeable.
- If there are any questions that need further clarification or further discussion, the Project Manager (PM) at the FDA should be contacted and told which questions require further feedback.
  - At the meeting, only these specific questions will be discussed.
- After the draft responses are received, if there is no further discussion needed about responses to the questions, the meeting can be canceled, and the draft responses provided by the FDA will be considered final.

# During the Meeting

- Most pre-IND meetings are allotted an hour of time.
- If the meeting is in teleconference format, the Sponsor-investigator should provide the FDA with a call-in number.
- Meetings will be chaired by an FDA staff member and will begin with introductions and a statement of the agenda.
- Only questions identified as needing further discussion to the FDA Project Manager (PM) will be discussed in the meeting.
- Presentations by sponsor-investigators or applicants are generally not needed.
- **Before the end of the meeting, summarize the important discussion points, agreements, clarifications, and action items.**

# After the Meeting

- After approximately 30 days, the FDA will provide the final written responses to the questions and note the discussions had during the meeting and the agreements made.
- The Sponsor-investigator should review the meeting minutes carefully and if there is a question that needs further clarification or there is a dispute of a specific FDA response, the Project Manager should be notified.
- The question or dispute will be reviewed and discussed within the FDA.
- The Sponsor-investigator's or applicant's concerns will be taken under consideration by the review division.
  - If the minutes are deemed to accurately reflect the meeting discussion, the point of contact will convey this decision to the sponsor-investigator or applicant and the minutes will stand as the official documentation of the meeting.
  - If, after discussions with the sponsor-investigator or applicant, the FDA deems it necessary to effect a change to the official minutes, the changes will be documented in an addendum to the official minutes. The addendum will also document any continued sponsor-investigator or applicant objections.

# Additional Resources

*For more information about pre-IND meetings with the FDA,  
click [here](#)*

*Click [here](#) for FDA's Guidance entitled "Formal Meetings Between the FDA  
and Sponsors or Applicants of PDUFA Products"*

*Click [here](#) for more information on Pre-IND Consultation Contacts*



Thank you!