



reImagining
drug development
for rare disease

Pre-IND Process Summary

Source: USA Food & Drug Administration

<https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/otat-pre-ind-meetings>

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Determining pre-IND Meeting Format

- The format for pre-IND meetings is typically either a teleconference or Written Response Only (WRO). OTAT rarely grants pre-IND meetings as face to face
- A sponsor may request a WRO meeting, or OTAT may determine that the WRO format is appropriate to meet the goals of the meeting request
- In determining the format of a pre-IND meeting, OTAT considers:
 - Whether the sponsor had a prior pre-IND meeting with OTAT for the same or similar product or indication.
 - Whether the sponsor had a previous or current IND for the same or similar product or indication.
 - Whether the preclinical testing and manufacturing process for the product use the same/similar platform as other product(s) submitted to OTAT by the same sponsor.
 - Whether the questions are straightforward or complex.
 - Whether the questions are adequately addressed in current FDA guidance and/or regulations.

Requesting a pre-IND

- Sponsors may email meeting requests to cberdcc_emails@fda.hhs.gov, with OTATRPMS@fda.hhs.gov in cc line
 - OTAT does not send an acknowledgement email or letter following OTAT's receipt of the pre-IND meeting request
- The meeting request should include a list of the specific objectives of the meeting and a list of questions (grouped by disciplines, e.g., CMC, P/T, clinical)
 - Relatively the same questions found in the briefing book in section _____
- By day 21, OTAT will send the decision to grant or deny the meeting request, along with the meeting date, if granted, or reasons for denial. OTAT will also provide the sponsor with a pre-submission tracking number (PTS) with the meeting confirmation.
- Meetings are scheduled for 60 minutes
- The pre-IND meeting will be scheduled to occur within 60 days of receipt of the meeting request.

pre-IND Package

- For a 60-minute meeting, a **maximum of 12 questions** (inclusive of sub-questions)
 - Written Response Only (WRO) is considered to be equivalent to 60-minute meetings. Therefore, the maximum of 12 questions (inclusive of sub-questions) is applicable.
- It is important to include background information sufficient to support the questions in the package. However, voluminous meeting packages are discouraged. Meeting packages are **typically 50 – 100 pages**. OTAT will not commit to reviewing packages greater than 250-300 pages or answering questions that require review of this much material.
- The meeting package for a pre-IND should **be submitted no later than 30 days before the scheduled date of the pre-IND meeting or WRO**
 - OTAT will state the date a meeting package is to be submitted in the meeting confirmation notice when the meeting is granted
- The meeting package should be submitted to the cberdcc_emailsub@fda.hhs.gov, with the assigned Regulatory Project Manager (RPM) and OTATRPMS@fda.hhs.gov in cc line
- The subject line of **the email should include the assigned PTS number** and meeting briefing package.
- **A cover letter should be included in the briefing package** with the inclusion of the assigned PTS number.

FDA Timelines

Itemized Requests	Number of Days
OTAT Response to Meeting Request**	21 days
Meeting Scheduled or WRO issued***	60 days
Meeting package due to OTAT	At least 30 days before the scheduled date of the meeting or WRO
Meeting Length	60 minutes
OTAT Preliminary Response to questions in the package to Sponsor (for teleconferences)	NLT* 2 days before the meeting
Sponsor's Response to FDA preliminary response (for teleconferences)	NLT than 24 hours before the meeting

*NLT – No Later Than

**Calendar days from FDA receipt of the meeting request to the date that OTAT will respond with the decision to grant or deny the meeting, as well as specifying the format and date of the meeting, if granted.

*** Calendar days from FDA receipt of the meeting request to date the meeting will be held, or the WRO will be issued.

Best Practices (teleconference)

- OTAT will send the preliminary response not later than 2 days before the scheduled teleconference
- The sponsor is expected to respond to OTAT's preliminary responses not later than 24 hours prior to the scheduled teleconference
- If the sponsor finds that OTAT's preliminary responses and advice are sufficiently clear and complete to obviate the need for further discussion, the sponsor should inform OTAT in writing as soon as possible so that OTAT may cancel the meeting.
 - These responses would then become the official OTAT responses to the sponsor's questions.
- If the sponsor wishes to continue with the meeting, the sponsor should identify which of the original questions in the briefing package they wish to discuss and list the questions in the proposed order of discussion.
 - As a rule, the meeting discussion follows the prioritized order of importance set by the sponsor, with the understanding that all questions may not be addressed due to time constraints.
- After receiving OTAT's preliminary response, the sponsor **should not** submit new questions and new information (e.g., alternative approaches or new proposals to address OTAT comments) that were not previously submitted in the original briefing package.

Best Practices (teleconference) Cont.

- Sponsors may choose to make a presentation at the beginning of the meeting. *(However, because OTAT staff will be familiar with the meeting package content and questions, OTAT recommends that sponsors forgo a presentation and use the allotted meeting time to obtain clarifications to OTAT's preliminary responses to the sponsor's questions).*
- OTAT will issue meeting minutes within 30 calendar days after the meeting. OTAT's version of the meeting minutes is official and the final record of the meeting.
- The sponsor may submit their version of the meeting minutes to the file to summarize their understanding of issues discussed at the meeting. However, OTAT may not review such submissions; therefore, the absence of an OTAT response to such submissions does not imply OTAT concurrence with the sponsor's version of the minutes
- If sponsors disagree with the content of OTAT's meeting minutes, OTAT's meeting minutes will not be altered except to correct a substantive mistake for the record

Post Meeting Follow-Up

WRO

- Simple requests for clarification of OTAT WRO may be sent to the Regulatory Project Manager (RPM) within 20 days after receipt of the WRO.
- The sponsor should include their request for clarifications for all disciplines in a single follow-up request.

Examples of such simple requests for clarification include:

Typos and misstatements by OTAT

The OTAT responses can be interpreted ambiguously and are unclear to the sponsor (e.g., “Did you mean A or B?”)

- If questions arise that are beyond clarification, the sponsor may submit these questions, alternative approaches, or new data to the original IND submission.
- OTAT will consider the follow-up request, and if determined to be limited to clarification, OTAT will issue a response in writing within 20 calendar days after receipt of the clarifying questions. If OTAT determines that a short teleconference would be the best format for follow-up, then OTAT will attempt to hold this informal teleconference within 20 days after receipt of the request for clarification. OTAT will not provide the sponsor with minutes for such informal teleconference.

Teleconference

- OTAT will not be able to address follow-ups or additional questions, via email or teleconference, after the meeting is held. If additional questions arise, the sponsor may submit the questions/alternative approaches or new data in the original IND submission.