AliraHealth

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Reduce Time to Market With Pre-IND Meetings

Reducing time to market is one of the biggest challenges companies face when seeking FDA approval on their drug development plans and clinical trials. A Pre-IND meeting is an effective means to speeding up the FDA approval process.

Pre-IND meetings reduce time to market in a variety of ways. These meetings can help companies:

1. Identify unnecessary studies (Pre-clinical/Clinical)
2. Ensure that studies are designed to provide meaningful information
3. Gain support for a proposed strategy
4. Minimize potential for clinical hold
5. Provide opportunity for creative exchange of ideas
6. Obtain regulatory insight
7. Minimize costs
8. Clearly define endpoints and goals of the development program
9. Allow early interactions and negotiations

What are the goals of a Pre-IND meeting with the FDA?

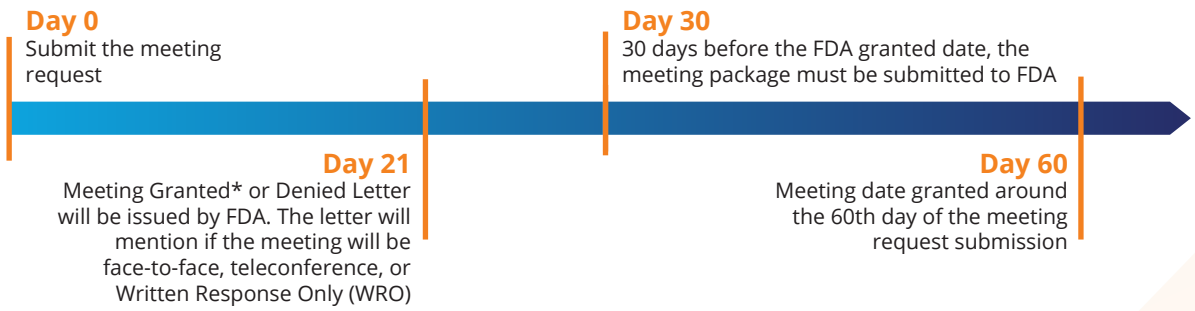
- ✔ Agreement with FDA that if the ex-U.S. studies qualify for support, the IND application will open a Phase II study stateside.
- ✔ Review animal studies to ensure they meet the requirements for initiating clinical studies in the U.S.
- ✔ Discuss the scope and design of Phase I/II studies.
- ✔ Discuss available methods to enhance expedited development: Orphan Drug designation, Fast Track designation, Accelerated Approval, and Animal Efficacy Rule, for example.
- ✔ Determine if CMC information is adequate for Phase I/II studies in the U.S.
- ✔ Present the summaries of ex-U.S. Phase I study results and confirm that data supports the final BLA to FDA.

Five common issues in Pre-IND meetings

1. Inadequate CMC information
2. Insufficient pre-clinical support
3. Unacceptable clinical trial design
4. Noncompliance with Good Clinical Practices (GCPs)
5. Lack of information on selection of dosage

Three best practices for a successful Pre-IND meeting

1 Follow a clear timeline to attain a Type-B Pre-IND meeting with FDA



**90% of meeting requests result in WRO. Mock FDA meetings should be held internally after the meeting package submission if a teleconference or face-to-face meeting is granted with FDA.*

2 Submit a detailed meeting request, including

- Meeting objective
- Proposed agenda, including estimated times needed for each agenda item
- Listing of specific questions categorized and grouped by discipline
- List of sponsor participants
- List of requested participants from CDER
- Quantitative composition of the drug proposed for use in the study
- Proposed indication
- Dosing regimen, including concentration, amount dosed, frequency, and duration
- Proposed meeting date (6-8 weeks in the future)
- Availability of the meeting package (at least 4 weeks before the proposed meeting date)

3 Create a comprehensive meeting package

- Overall program synopsis
- Relevancy of the animal efficacy rule
- Clinical study synopsis
- Results for in vitro and early in vivo toxicology
- Rationale for safety, based on toxicological profile and safety margin
- Brief description of the manufacturing scheme for the active pharmaceutical ingredient (API) and formulation for clinical study
- Brief assay descriptions
- Full description of the development plan
- Copy of the meeting with updates to reflect the most current information request

Reduce your time to market with a successful Pre-IND meeting request. Connect with our strategy and planning experts to get started.

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