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Meetings with FDA

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MEETINGS WITH THE FDA

Submit IND

Pre-Human Research

Phase 1

Phase 2

Phase 3

Submit NDA

FDA Review

Phase 4

Pre-IND Meeting

End of Phase 1 Meeting

End of Phase 2 Meeting

Pre-NDA Meeting

Adv Cmte

Final Labeling Discussions

Other meetings as special issues arise
Meetings

• Pre-IND
• End of Phase 1 (EOP1)
• End of Phase 2 (EOP2)
• Pre-NDA/pre-BLA
• How do I request a meeting?
• Meeting granted-What to expect afterwards
• Comments and useful tips
Pre-IND Meeting

- 21 CFR 312.82 (a)
- Objectives:
  - to review and reach agreement on the design of animal studies needed to initiate human testing
  - To discuss the scope and design of Phase 1 testing, plans for studying the drug product in pediatric populations and best approach for presentation and formatting of data in the IND
Pre-IND meetings (When, Why)

- Novel indication
- No current Guidance Documents
- Unique molecular entity, studies or indications
- New sponsors or new to area of drug development
- Problematic Pharm/Tox signals
- NME
- Avoid protocol changes
Pre-IND meeting

• How do I request a pre-IND meeting?
  – Know your FDA Division
  – All pre-IND submissions addressed directly to the responsible Chief Project Management Staff (CPMS) or other designated Division Personnel until a PIND file is opened
Pre-IND meeting (contd)

• How does FDA track pre-INDs?
  – Divisions assign a pre-IND number, and a PIND file is open. No regulatory prerogatives, only for tracking/filing purposes
  – Generally, as soon as a PIND file is established, an acknowledgment letter is sent to the sponsor
  – All future communications should refer to this PIND number
  – PIND number is converted to IND number after IND submission (number carries over)
End of Phase 1 Meeting (EOP1)

• 21 CFR 312.82

• Generally reserved for drugs for severely-debilitating and life-threatening illnesses that are reviewed under the accelerated approval program

• Objective:
  – to review and reach agreement on the design of Phase 2 controlled clinical trials
  – To discuss the need for, as well as design and timing of studies in pediatric patients
End of Phase 2 Meeting (EOP2)

• 21 CFR 312.47 (b) (1)

• A productive EOP2 meeting can help prevent misunderstandings between Division and Sponsor regarding the drug development program, thus avoiding costly and time consuming attempts at correction later in the process.
EOP 2 Meeting (cont)

• Objectives:
  – To obtain agreement on pivotal study designs, and safety and efficacy endpoints for Phase 3 studies
  – To update on progress of PK studies and discuss additional studies needed
  – To assure that pre-clinical data with regard to duration, route of administration, and formulation are supportive of the dose to be used in clinical trials
• CMC
  – To discuss approach to specifications and test methods
  – To discuss “to be marketed” formulation
  – To evaluate appropriate protocols
  – To identify other issues or potential problems (novel regulatory or technical concerns)
EOP2 meeting briefing package

- Summaries of Phase 1 and Phase 2 investigations
- Summary information on plans for Phase 3 trials
- Specific protocols for Phase 3 studies
- Plans for pediatric studies
- Plans for additional non clinical studies (if required)
Pre-NDA/BLA Meetings

- 21 CFR 312.47 (b) (2)
- Critical interaction between CDER staff and the sponsor in ensuring the submission of a well organized and readily reviewable NDA/BLA
Pre-NDA/BLA Meetings (cont)

• Objectives:
  – To determine the adequacy of the sponsor’s dossier for the submission of an NDA/BLA
    • For new applications, all electronic submissions must be in eCTD format
  – To agree on format and content of the application (any specific needs?)
  – To determine status of ongoing studies to address pediatric safety and efficacy
Pre-NDA/BLA Meetings (cont)

– Early discussions on priority or standard review, and need for Advisory Committee meetings
  • Advisory Committee meeting is the default for all New Molecular Entities (NMEs)

– May include discussion on the need for REMS (Risk Evaluation and Mitigation Strategies) plans and proposed observational studies
How do I request a meeting with FDA?

• Submission of a meeting request
Guidance for Industry, “Formal Meetings with Sponsors and Applicants for PDUFA Products”

- Product name and application number (if applicable)
- Chemical name and structure
- Proposed indication (s)
- The type of meeting being requested (e.g., Type A, Type B, or Type C)
Guidance for Industry (cont)

- A brief statement of the purpose of the meeting
- A list of specific objectives/outcomes expected from the meeting
- A preliminary proposed agenda
- A draft list of questions, grouped by discipline
Guidance for Industry (cont)

• A list of all individuals (including titles) who will attend the meeting
• A list of Agency staff requested by the sponsor or applicant to participate in the proposed meeting
• The approximate date on which supporting documentation will be sent to the Division
• Suggested dates and times (e.g., morning or afternoon) for the meeting
Establishing the meeting

• The assigned PM will contact sponsor to negotiate date/time of the meeting

• Discussions on materials needed (briefing package), and number of copies
  – “Not too big, not too small”
  – Table of contents
  – List of questions
  – Organized with tabs
  – Submitted on time
  – Adequate number of copies
Establishing the meeting (cont)

• Communication (letter, fax, e-mail) sent acknowledging the meeting date/time, location, attendees

• Arrival and meeting protocols
## Types of Meetings

<table>
<thead>
<tr>
<th>Type</th>
<th>A</th>
<th>B</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confirmation of scheduling</td>
<td>14 days</td>
<td>21 days</td>
<td>21 days</td>
</tr>
<tr>
<td>Held no later than</td>
<td>30 days</td>
<td>60 days</td>
<td>75 days</td>
</tr>
<tr>
<td>Briefing package</td>
<td>2 weeks</td>
<td>4 weeks</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Description</td>
<td>Dispute resolution, Clinical holds, Special Protocol Assessment</td>
<td>preIND, EOP1, EOP2, Pre NDA/BLA</td>
<td>Any other than type A or B</td>
</tr>
</tbody>
</table>
Meetings

• For every external meeting there is at least one internal team meeting
  – Pre-meeting/internal meeting
  – Usually, preliminary answers to questions are sent to the sponsor 24-48 hours before the meeting
  – Industry/Sponsor external meeting
Pre-meeting

• Work with Regulatory Project Manager (RPM) to establish agreeable agenda and acceptable list of questions
  – Foreign visitors?

• Notify RPM of any last minute changes (list of attendees, audio/visual equipment)
During the meeting

• Summarize key discussion points, agreements, and action items
• Make sure that your questions have been addressed
Post meeting

• Provide the Division with any meeting hand-outs and/or slides
• Official FDA minutes will be issued within 30 days of the meeting
• Review minutes and notify Division of any discrepancies/clarifications
• Follow-up on any requests
Meetings are not appropriate when

- Information can be condensed in a summary
- Timing is premature
- Right people are not present
- There is missing information
General comments

• Face to face meetings are not the only way to obtain feedback and advice
• Schedule meetings to discuss specific issues
• Utilize guidance documents to the fullest
• “What ifs” are difficult to address
• Meetings are more productive with focused and specific questions. Do not schedule meeting to obtain pre-review of data
• The Agency will provide guidance/comments on your proposals
Tips

- Communicate clearly with the FDA RPM
- Work with RPM to determine agreeable time/day for the meeting
- Know how many copies of the briefing package are needed
- Organize the briefing package with tabs
- Submit focused questions
More tips

• Update changes in attendees
• Presentations?
• Do not add new topics or issues to the original agenda
• Do not ask open ended questions
• Make sure all your concerns/questions have been addressed (or acknowledged) before you leave the meeting
Resources

• [www.fda.gov](http://www.fda.gov)

• [http://www.fda.gov/Drugs/default.htm](http://www.fda.gov/Drugs/default.htm)
  – Guidance, Compliance and Regulatory Information
  – About the Center for Drug Evaluation and Research

• [http://www.fda.gov/BiologicsBloodVaccines/default.htm](http://www.fda.gov/BiologicsBloodVaccines/default.htm)
  – Guidance, Compliance and Regulatory Information (Biologics)
  – Contacts in the Center for Biologics Evaluation and Research