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» Meetings with the FDA: *Basic*

□ Session Objectives

▪ Attendees will learn:

- Regulations versus Guidelines
- Types of Meetings
- Purpose Meetings
- Pros/Cons of Meeting Formats
- How to Prepare the Meeting Request Letter

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>> Regulations vs. Guidelines

❑ Regulations versus Guidelines

▪ Regulation: 21 CFR 312.XX

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312>

- Regulations = Law (must be followed)
- 21 CFR 312.47 describes meetings with the FDA (focuses on End-of-Phase 2 and Pre-NDA Meetings)

▪ Guideline: Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products (March 2017)

- Guidelines represent the FDA's current position on a given topic and are not binding on either the FDA or Sponsors



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>> Types of Meetings

❑ Three types of meetings described in guidelines:

- Type A Meeting (Dispute Resolution, Clinical Hold, Special Protocol Assessment)
- Type B Meeting (Pre-IND Meeting, End-of-Phase 2, Pre-NDA/BLA)
- Type C Meeting (Any meeting that is not a Type A or Type B meeting)

▪ The general purpose of meetings with the FDA

- From the regulations: *"Meetings between a sponsor and the agency are frequently useful in resolving questions and issues raised during the course of a clinical investigation."*
- Each meeting with the FDA will have a specific purpose



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>> Types of Meetings

- ❑ Three types of meetings described in guidelines (cont'd):
 - **Type A Meeting (Dispute Resolution, Clinical Hold, Special Protocol Assessment)**
 - Generally scheduled within 30 days
 - To help with “stalled” development programs
 - **Type B Meeting (Pre-IND Meeting, End-of-Phase 2, Pre-NDA/BLA)**
 - Generally scheduled within 60 days
 - **Type C Meeting (Any meeting that is not a Type A or Type B meeting)**
 - Generally scheduled within 75 days



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>> Pre-IND Meetings

- ❑ **Pre-IND Meetings**
 - **Typically, purpose is to identify and address issues prior to IND submission**
 - Address CMC concern/issues
 - Design of toxicology studies
 - Design of Phase 1 study
 - **Nearly all Sponsors seeking Pre-IND Meeting nowadays**
 - Helps to avoid a clinical hold once the IND is filed
 - Used to add value to asset/aid in fund raising



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Contents of Meeting Request Letter

□ Contents of Meeting Request Letter:

- **Cover Letter**
 - Brief introduction to product
 - Provides contact information for FDA
 - Form FDA 1571
- **Application Number**
 - The Pre-IND number assigned to project by FDA
 - Can be requested in advance of submitting letter (or assigned by FDA upon receipt of letter)
 - Used on all future correspondence with FDA
- **Product Name**
 - Company code name (AB-123) or generic name



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Contents of Meeting Request Letter

□ Contents of Meeting Request Letter (cont'd):

- **Chemical name, established name (if available) and structure**
- **Proposed regulatory pathway**
 - 505(b)(1) for original NDAs/BLAs or 505(b)(2) for previously approved products
- **Proposed indication**
 - Should be worded as it is likely to appear in the Package Insert at the time of product approval
- **Meeting Type being Requested (Type A, Type B, or Type C)**
 - FDA generally accepts the type of meeting requested but can change it (Type B > Type C) but this is rare



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Contents of Meeting Request Letter

□ Contents of Meeting Request Letter (cont'd):

- **Pediatric Study Plans**
 - Generally “NA” (not applicable) for Pre-IND Meetings
- **Human Factors Engineering Plans**
 - Related to medical devices
- **Combination Product Information**
 - Related to drug-device combination products
- **Suggested Dates and Times**
 - Needs to comply with meeting timelines (for example, 60+ days for a Pre-IND Meeting)
 - Time generally relates to morning/afternoon



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Contents of Meeting Request Letter

□ Contents of Meeting Request Letter (cont'd):

- **Proposed Questions**
 - Grouped by discipline: CMC, nonclinical, clinical
 - Most important section of Meeting Request
 - ✓ Identifies the disciplines that the FDA has to invite to the meeting which impacts scheduling
 - Should include a brief explanation of the purpose and context of the question



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Contents of Meeting Request Letter

□ Contents of Meeting Request Letter (cont'd):

▪ Proposed Questions (cont'd)

➤ Example

- ✓ “Does the Division agree that the completed and planned nonclinical studies are adequate to support the initiation of the proposed Phase 1 study?”
 - **Purpose and Context:** <Sponsor> would like to confirm with the Division that the completed/planned nonclinical pharmacology, pharmacokinetic, safety pharmacology, and toxicology studies to be included in the IND will be adequate to initiate the proposed clinical study.



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Contents of Meeting Request Letter

□ Contents of Meeting Request Letter (cont'd):

▪ Proposed Meeting Format

- Face-to-face (most commonly requested), teleconference, “written responses only” (FDA responds in writing)
- FDA generally tries to honor request but can change/decide meeting format

▪ Date Meeting Package will be Submitted

- Must confirm with timeline in guideline
- For a Pre-IND Meeting: “<Sponsor> will submit the Meeting Package no later than 30 days in advance of the scheduled meeting.”



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Contents of Meeting Request Letter

□ Contents of Meeting Request Letter (cont'd):

▪ Purpose of the Meeting

- A brief statement regarding the background of the issues, the general nature of the questions, the status of the development program, etc.
- Generally 1-2 paragraphs

▪ Objectives of the Meeting

- A short list of the specific objectives/outcome of the meeting
- Example: “<Sponsor> expects to understand the Division’s nonclinical study requirements for initiating the proposed Phase 1 study.”



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Contents of Meeting Request Letter

□ Contents of Meeting Request Letter (cont'd):

▪ Proposed Agenda

- Introductions: 5 minutes
- Discussion: 50 minutes
- Summary: 5 minutes

▪ Sponsor’s Attendees

- List the names, titles, role of attendees
- For non-US attendees, a meeting attendance form must be submitted ~2 weeks prior to the meeting



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Contents of Meeting Request Letter

□ Contents of Meeting Request Letter (cont'd):

▪ Requested FDA Attendees

- Generally, the list of FDA attendees is established by the questions
- Example: “<Sponsor> kindly requests the following attendees from the Division: Division Director (name), Supervisory Medical Officer, Supervisory Pharmacologist, Supervisory Chemist, and Regulatory Project Manager.”



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General Comments

□ General Comments Regarding the Meeting Request Letter

- Should be submitted when Sponsor is confident that the Meeting Package will be available when required
 - If Meeting Package is submitted late, the FDA can cancel the meeting
- FDA will notify Sponsor regarding the meeting in ~ 21 days for a Pre-IND Meeting
- Important to remember that Sponsor has opportunity to modify questions and attendees in the Meeting Package
 - Sponsor can add/delete/re-word questions in Meeting Package as long as no new disciplines are added
 - Attendee list can change up to 2 weeks prior to the meeting



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>> Meetings with the FDA: *Basic*

❑ Next Session: Meetings with the FDA: *Advanced*

▪ Attendees will learn about

- How to prepare the Meeting Package
- Operational activities associated with the meeting
 - ✓ Preliminary responses, meeting preparation, attending the meeting, etc.
- Recommendations for a successful meeting

❑ Questions?



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