

Meetings with the FDA

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#KIOSC #TRAINING

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» Meetings with the FDA

□ Session Objectives

▪ Attendees will learn:

- Regulations versus Guidelines
- Types of Meetings
- Purpose Meetings
- Meeting Formats
- How to Prepare the Meeting Request
- How to Prepare the Meeting Package
- Operational Activities for Attending the Meeting

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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 following meeting request
 - To help with “stalled” development programs
 - **Type B Meeting (Pre-IND Meeting, End-of-Phase 2, Pre-NDA/BLA)**
 - Generally scheduled within 60 days following meeting request
 - **Type C Meeting (any meeting that is not a Type A or Type B meeting)**
 - Generally scheduled within 75 days following meeting request



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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
 - Confirm Sponsor will be “ready” to submit IND
 - Can be “data driven” or “plan driven”
 - 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

□ Contents of Meeting Request:

- **Cover Letter**
 - Brief (1 page) introduction to product
 - Provides contact information for FDA
 - Includes Form FDA 1571
- **Application Number**
 - The Pre-IND number assigned to project by FDA
 - Can be requested in advance of submitting meeting request (or assigned by FDA upon receipt of meeting request)
 - Used on all future correspondence with FDA (including subsequent IND)
- **Product Name**
 - Company code name (AB-123) or generic name



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» Contents of Meeting Request

□ Contents of Meeting Request (cont'd):

- **Chemical name, established name (if available) and structure**
- **Proposed regulatory pathway**
 - 505(b)(1) for original NDAs or 505(b)(2) for previously approved products
 - 351(a) for original BLAs or 351(k) 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)



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» Contents of Meeting Request

□ Contents of Meeting Request (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

□ Contents of Meeting Request (cont'd):

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



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» Contents of Meeting Request

□ Contents of Meeting Request (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

□ Contents of Meeting Request (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
- With COVID-19, there are no face-to-face meetings

▪ 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

□ Contents of Meeting Request (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

□ Contents of Meeting Request (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

□ Contents of Meeting Request (cont'd):

▪ Requested FDA Attendees

- Generally, the list of FDA attendees is established by the questions
- Example: "In addition to Dr. <>, Division Director, the Sponsor requests that disciplines within the Division/FDA participate in the meeting based on the issues to be discussed."



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» General Comments

□ General Comments Regarding the Meeting Request

- 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
- Can be helpful to contact the Division (Senior Regulatory Project Manager) 3-5 days following submission of meeting request to confirm receipt
- 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

- ☐ Questions regarding the types of meetings or the meeting request?



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>> Meetings with the FDA

- ☐ Meeting Granted Letter
 - Will receive a “Meeting Granted” letter from the FDA ~21 days after submitting the Meeting Request
 - Will include date, time, type, and location of meeting
 - Number of desk copies to be submitted (and when) if meeting request was submitted in paper format
- ☐ *Note: There is considerable overlap between the Meeting Request and Meeting Package as indicated by red font in the slides that follow*



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» Contents of Meeting Package

□ Contents of Meeting Package:

- **Cover Letter**
 - Reference to Meeting Granted Letter
- **Application Number**
 - Will be included in Meeting Granted Letter (if not obtained in advance)
 - PIND 123456 (Preliminary IND #)
- **Product Name**
 - Company code name (AB-123) or generic name
- **Chemical name, established name (if available) and structure**
- **Proposed regulatory pathway**
 - 505(b)(1) or 505(b)(2) for drugs or 351(a) or 351(k) for biologicals



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» Contents of Meeting Package

□ Contents of Meeting Package (cont'd):

- **Proposed Indication**
- **Dosage Form, Route of Administration, and Dosing Regimen**
 - For example: AB-123 will be supplied as 100 mg capsules for oral administration. The anticipated dosing regimen is once daily.
- **Pediatric Study Plan**
- **Human Factors Engineering Plan**
- **Combination Product Information**
- **Updated List of Sponsor's Attendees**
 - The list of attendees can be updated/changed from what was in the Meeting Request



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» Contents of Meeting Package

□ Contents of Meeting Package (cont'd):

▪ Background Information

- **Brief** history of the development program and relevant communications with the FDA before the meeting
 - ✓ One to two-page summary of the development program and a summary of previous interactions with FDA
 - Generally not applicable for a Pre-IND Meeting but can be substantial for a Pre-NDA Meeting
- Substantive changes in product development plans
 - ✓ Again, generally not applicable to Pre-IND Meetings
- Current status of product development
 - ✓ Include any non-US activities



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» Contents of Meeting Package

□ Contents of Meeting Package (cont'd):

- **Purpose of the Meeting**
- **Proposed Agenda**
- **Final Questions for Discussion**
 - You can add/delete questions that were in the Meeting Request; however, you can not add new disciplines
- **Data to Support Discussion**
 - Provide sufficient detail so that the FDA can answer the questions
 - Summaries of completed studies
 - Protocols/protocol outlines of planned studies



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» Operational Activities

- ❑ **Operational Activities Associated with the Meeting**
 - **No later than 2 weeks prior to the meeting, submit to the FDA a “Foreign Visitor Data Request Form” for face-to-face meetings**
 - **Name, country, date of birth, passport number, etc.**
 - **Will not be able to attend meeting without it**
 - **Preliminary Responses**
 - **Approximately 2-3 days prior to the meeting, the FDA will issue their “preliminary responses” to the questions**
 - ✓ **If all questions have been answered satisfactorily, the Sponsor can cancel the meeting without prejudice**
 - ✓ **If the meeting is to continue, it is advisable to identify those questions for which issues are still outstanding**
 - **Only those questions will be discussed at the meeting**
 - **Indicate to the FDA why the Sponsor would like to discuss the issue**

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» Operational Activities

- ❑ **Operational Activities Associated with the Meeting (cont'd)**
 - **Meeting preparation/rehearsal**
 - **Every Sponsor takes a different approach**
 - ✓ **No rehearsal > 2-3 days of rehearsal**
 - ✓ **Generally held in hotel near the FDA (for face-to-face meetings)**
 - ✓ **Who will be moderator of the meeting?**
 - ✓ **Who will take notes?**
 - **Go over outstanding issues**
 - ✓ **Who from the Sponsor will address the issues?**
 - ✓ **Decide what will be important to get out of the discussion**
 - ✓ **Slides/presentations are generally not advised; however, if the issue is complicated and slides would be beneficial, they need to be submitted to the FDA prior to the meeting (confirm with RPM at FDA beforehand)**

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» Operational Activities

❑ Operational Activities Associated with the Meeting (cont'd)

▪ Attending the Meeting

- Arrive at FDA early (one hour before the meeting)
- Will check in at front desk and be given a badge
 - ✓ You MUST have picture ID/passport
- Approximately 5 minutes prior to the scheduled start of the meeting, you will be escorted to the meeting room
- You will go through a metal detector much like the airport
- Generally, FDA attendees sit on one side of the table and Sponsor attendees the other
- Introductions will be brief: Name, title, affiliation



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» Operational Activities

❑ Operational Activities Associated with the Meeting (cont'd)

▪ Attending the Meeting (cont'd)

- After introductions, moderator generally introduces the first issue to be discussed
- Some Divisions at FDA generate the Meeting Minutes in “real time” during the meeting
- Once all issues have been discussed, moderator will summarize the key agreements reached during the meeting
- Meeting is adjourned and Sponsor is escorted to the lobby



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>> Operational Activities

☐ Operational Activities Associated with the Meeting (cont'd)

▪ Post Meeting Activities

- Have an immediate “debrief” to make sure all critical aspects/agreements at the meeting have been captured and understood
- Although the FDA will issue the official Meeting Minutes, plan to submit the Sponsor’s “Draft” Meeting Minutes to the FDA within 2 weeks (ideally sooner) of the meeting
- FDA will issue the official Meeting Minutes ~30 days after the meeting
 - ✓ Sponsor can ask FDA to reconsider if there is a difference of opinion regarding a particular issue



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>> Next Session

☐ Questions regarding the Meeting Package or operational activities related to FDA meeting?

☐ Next Session: The Investigational New Drug (IND) Process: Part 1

- The differences between a commercial IND and a Sponsor-Investigator IND
- When an IND is required (and when it is not)
- If one can promote or charge for an investigational new drug
- Common Technical Document (CTD) structure related to IND submissions
 - Detailed review of IND content and format



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