# FDA Meeting Types with CDER and CBER

## WHY MEET WITH FDA?

For drug or biologic developers, we recommend that you meet with and discuss your development plans with the United States Food & Drug Administration (FDA) throughout your development program. Early and successful interactions with the FDA can reduce both costs and time to approval. To meet with the FDA, you will need to decide on your preferred format for the meeting (face-to-face, teleconference, or written responses), and submit a formal meeting request accompanied or followed closely by an informational package. Once the FDA has reviewed your meeting request, they will determine whether to grant the meeting and determine the meeting format.

### FDA GUIDANCE ON MEETINGS

The FDA has issued a formal guidance on this entire process, Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products Guidance for Industry.

## TYPES OF FDA MEETINGS WITH CDER AND CBER

Below is a summary of the different types of FDA Meetings, when they apply, examples of, and the timing parameters of each meeting type.

## TYPE A MEETINGS: **URGENT SITUATIONS**

### Timing Parameters of Type A Meetings:

- Discuss with review division prior to submitting request
- Day 0: Submit meeting request and briefing package together
- Day 14: FDA accepts or denies meeting, specifies meeting format, and schedules date
- Within 30 days: Meeting held with FDA

### Examples of Type A Meetings:

*Stalled programs and important safety issues*

- Dispute resolutions (Dispute resolution examples = scientific or medical disputes regarding INDs)
- Meetings to discuss clinical holds
- SPA non-agreement
- Post-action meetings requested within 3 months of action (complete response letter)
- Meetings requested within 30 days of a refuse-to-file letter

## TYPE B MEETINGS: **SPECIFIC DEVELOPMENT PROGRAM MILESTONES**

### Timing Parameters for Type B Milestone Meetings:

- Day 0: Submit meeting request
- Day 21: FDA accepts or denies meeting, specifies meeting format, and schedules date
- Near Day 30: Briefing package due 30 days prior to meeting date
- Within 60 days: Meeting held with FDA

### Timing Parameters for End of Phase (EOP)* Meetings:

- Day 0: Submit meeting request
- Day 14: FDA accepts or denies meeting, specifies meeting format, and schedules date
- Near Day 20: Briefing package due 50 days prior to scheduled meeting
- Within 70 days: Meeting held with FDA

### Examples of Type B Milestone Meetings:

- Pre-IND meetings
- Pre-emergency use authorization meetings
- Pre-NDA/ pre-BLA meetings
- Post action meetings requested more than 3 months after action
- Meetings regarding REMS and other post-marketing requirements
- Meetings to discuss product development for products granted breakthrough therapy designation

### Examples of End of Phase Meetings:

- Certain end-of-phase 1 (i.e., for products that will be considered for approval under 21 CFR 312 subpart E or 21 CFR subpart H – new drugs for serious or life-threatening illnesses)
- End-of-phase 2 or pre-phase 3 meetings

## TYPE C MEETINGS: **SPECIFIC TOPICS WITH LESS URGENCY**

### Timing Parameters of Type C Meetings:

- Day 0: Submit meeting request
- Day 21: FDA accepts or denies meeting, specifies meeting format, and schedules date
- Near Day 28: Briefing package due 47 days before scheduled meeting
- Within 75 days: Meeting held with FDA

### Examples of Type C Meetings:

- All meetings that are not captured in Type A or B
- Use when specific information or concurrence is required from FDA (e.g. change in product formulation, use of biomarker as surrogate endpoint)

## LEARN MORE

Developing a strong relationship with the FDA is crucial to ensuring that the Agency is knowledgeable about your product and supports its development pathway. Formal meetings with the FDA will strengthen this relationship and allow the Agency to provide input on your product and program's development plan. Veristat regulatory experts are highly experienced with preparing for, attending and facilitating meetings with FDA.

## CONTACT VERISTAT

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