Public Workshop on Meeting Management Best Practices
July 22, 2024
Virtual Q&A

During the workshop, a substantial number of questions were submitted by virtual attendees of the meeting. At first, a few initial questions were presented to the panelists and were answered during the meeting. Due to the influx of new questions after the first few were answered and the limited time for panelist discussions, the remaining questions were deferred until after the workshop. Answers to the virtual questions are provided in the tables below.

Meeting Requests & Background Packages Questions*	Answers
If a sponsor requests a meeting outside of the PDUFA timeline, does it count against the Agency's performance goal?	It does not. *Answered live during the workshop*
In the meeting request, how should we explain why a face-to-face is being requested?	Specify what parts of the request would be served best by a face-to-face meeting, and how a live meeting interaction would increase the ability to answer and discuss specific questions. This would be particularly helpful for meeting types in which the background packages are not required to be sent at the time of the request. *Answered live during the workshop*
Is there a limit to the number of pages for the briefing book? Does that include the Appendices?	Overall, there is no limit to the number of pages for briefing books. But best practice is usually 50-100 pages, and anything over 250-300 pages is voluminous. *Answered live during the workshop*
Is it recommended to contact the RPM prior to a meeting request submission?	It would be helpful to give RPMs a heads-up that a meeting request will be coming in, particularly for those meeting types with shorter timelines (e.g., Type A). *Answered live during the workshop*
Is putting reports in briefing package appendices acceptable or is the summary of the report sufficient?	As noted in FDA's formal meetings guidance[1], "Protocols, full study reports, or detailed data generally are not appropriate for meeting packages; the summarized material should describe the results of relevant studies and clinical trials with some degree of quantification and any conclusion about clinical trials that resulted. "A summary is sufficient. *1 Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products Guidance for Industry (September 2023)*

Is there a number of questions that generally becomes too much?	According to FDA guidance, meeting requests should generally include no more than 10 total questions, including sub-questions. *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products Guidance for Industry (September 2023)*
Is it recommended for Sponsors to put a "Sponsor position" for each question to allow FDA to better understand if a question is simple vs. complex?	While knowing the "sponsor position" on each question may not necessarily reveal question complexity, it could more easily highlight points where FDA may have a different viewpoint.
In cases where a cross-Center consult is required, may this result in additional response timelines for the WRO or meeting to be established?	The Prescription Drug User Fee Act meeting management procedural goals are unchanged by consults, and efforts are made to honor those goal dates. However, the need to obtain input from outside the Center can potentially delay the response due to competing priorities and goals for other Centers.

Meeting Management for all Meeting Types Questions*	**Answers**
Can you please elaborate on which CMC questions can be part of a Type B EOP2 meeting?	According to the FDA guidance, the EOP2 meeting should focus on the CMC-specific questions on the planned phase 3 studies. Typically, the meeting will also include a discussion identifying additional information to support a marketing application. Please refer to the IND Meetings for Human Drugs and Biologics Chemistry, Manufacturing, and Controls Information Guidance for more information on CMC issues that can be addressed in EOP2 meetings.
Could FDA please provide advice to sponsors who, for a single drug, may have multiple indications across multiple review divisions? For program level questions like clinical pharmacology and/or toxicology that may be indication agnostic, how should sponsors approach these matters with FDA?	FDA described that it in these cases, it is particularly important to speak to the RPM to determine the best path forward for making the request. FDA has mechanisms to provide advice over multiple disciplines for questions that are geared to multiple indications, and the RPM will be able to advise on this process. Oftentimes, this will result in a multidisciplinary meeting where one division takes the lead, and others are there to provide input and support. FDA noted that they do encourage sponsors to provide information on who they think should be attending the requested meeting, but it is ultimately up to the discretion of the FDA to finalize the list of attendees based on the request. *Answered live during the workshop* That being said, it is important to recognize that while the sponsor may believe a particular issue or question is program

	agnostic, the FDA may view it differently based on prior experience and may recommend individual program development specific meetings to receive program specific advice.
Does FDA encourage Sponsors to not cancel a scheduled meeting?	According to FDA guidance, occasionally, circumstances arise that necessitate rescheduling or canceling a meeting. If a meeting needs to be rescheduled, it should be rescheduled as soon as possible after the original date. A new meeting request should not be submitted. However, if a meeting is canceled, the FDA will consider a subsequent request to schedule a meeting to be a new request (i.e., a request that merits a new set of time frames). Requesters and the FDA should take reasonable steps to avoid rescheduling and canceling meetings (unless the meeting is no longer necessary). *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products Guidance for Industry (September 2023)* FDA noted during the workshop that if a sponsor is debating whether to cancel their formal scheduled meeting with FDA following the receipt of preliminary responses, FDA would recommend proceeding with the meeting to maintain the opportunity to receive follow-up clarification. Industry agreed with this, stating that meetings should only be cancelled when it seems as though all parties agree that all questions were sufficiently answered. *Answered live during the workshop*
Can the Agency speak to best practices for the inclusion of input from key opinion leaders and/or patients, when these viewpoints are deemed by the Sponsor to be important for the topics of discussion? How can industry best incorporate these perspectives into meeting briefing materials as well as meeting discussions?	Sponsors may include this information in the briefing materials to provide background for the questions posed. Sponsors may also invite stakeholders to participate in the meeting discussions. Input from patients, patient groups, and key opinion leaders can provide important perspective for the FDA team to consider, particularly for rare diseases. FDA recommends that stakeholder input included in the briefing package be provided in a manner that clearly describes how the input was collected and how the sponsor anticipates that the input will inform the discussion of the specific question for which it is being submitted. FDA also recommends that if the sponsor anticipates that input from specific FDA subject matter experts (e.g., the Division of Clinical Outcome Assessments) will be necessary, their participation is explicitly requested as part of the meeting request.

	The Agency encourages sponsors to prioritize issues or points of clarification that will be discussed during the allotted meeting hour to ensure the meeting outcomes can be achieved. Sponsors could allot time on the agenda for additional topics to be discussed later in the meeting if time allows. *Answered live during the workshop* You may refer to the Patient Focused Drug Development Methodologic Guidance Series for additional information on enhancing the incorporation of the patient's voice in medical product development and regulatory decision making.
How are pre-IND meeting requests and background packages submitted to the Agency if we do not have an IND to submit via eCTD? Can they be submitted via paper?	For CBER, to submit a pre-IND in eCTD, sponsors should request a PTS number following procedures in SOPP 8117: Issuing Tracking Numbers in Advance of Electronic Submissions in eCTD Format. CBER also accepts submissions exempt from the 745(A) guidance via email at CBERDCC_eMailSub@fda.hhs.gov (please see https://www.fda.gov/about-fda/about-center-biologics-evaluation-and-research-cber/regulatory-submissions-electronic-and-paper). Requesters should submit the archival meeting package to the relevant application(s) (e.g., pre- IND, IND, NDA, BLA or PTS (CBER)) via the electronic gateway or, in CDER, sponsors should contact the RPM to obtain a pre-IND number and may submit via the CDER Nextgen Portal (https://cdernextgenportal.fda.gov/), as applicable. Sponsors may obtain a pre-IND number prior to submission. For additional ways to submit to CBER, please see https://www.fda.gov/about-fda/about-center-biologics-evaluation-and-research-cber/regulatory-submissions-electronic-and-paper. If necessary, noncommercial IND holders may also submit the package via the appropriate Center's document room. *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products Guidance for Industry (September 2023)*
When a sponsor submits a meeting request with briefing book, is it typical for FDA to still grant the meeting in 75 days or sooner for Type C?	FDA strives to follow the timelines for scheduling meetings based on the type of meeting granted. The due date for briefing materials ("background package") is different for each meeting type and is intended to afford sufficient time for FDA to thoroughly review and respond to the questions. If sponsors elect to submit the background package earlier,

	FDA will accept and begin review; however, that will not impact the timing of the meeting scheduling as that is dictated by the meeting type as noted above. FDA will aim to schedule the meeting within 75 calendar days from receipt of the meeting request regardless if it contains a briefing book.
Why would FDA convert a Type C meeting to a Type B, and does it then keep the company from requesting another Type B meeting?	FDA would convert a Type C meeting to a Type B because it was deemed a milestone meeting which may include any of the following: • Pre-IND meetings • Pre-emergency use authorization meetings • Pre-NDA/Pre-BLA meetings • Post-action meetings when requested within three months after receiving an FDA regulatory action other than approval • Meetings regarding REMS or post-marketing requirements • Meetings to discuss the overall development program for products granted breakthrough therapy designation Generally, with the exception of products granted breakthrough therapy designation status, the FDA will not grant more than one of each of the Type B meetings for each potential application (e.g., IND, NDA, BLA) or combination of closely related products developed by the same requester (e.g., same active ingredient but different dosage forms being developed concurrently), but the FDA can do so when it would be beneficial to hold separate meetings to discuss unrelated issues. For example, it may be appropriate to conduct more than one end-of-phase 2 meeting with different review divisions for concurrent development of a product for unrelated claims or a separate meeting to discuss manufacturing development when the clinical development is on a different timeline. *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products Guidance for Industry (September 2023)*

Meeting Minutes and Follow Up Opportunities Questions*	**Answers**
How long should a sponsor wait after the PDUFA goal to escalate delayed meeting minutes to the Chief RPM?	A sponsor should escalate delayed meeting minutes to the Chief RPM if they have not received a response from their RPM after multiple attempts.
What is the experience of creating live meeting minutes? How often is	Within CDER, majority of divisions do not create live meeting minutes with the exception of the Office of Oncologic

that process used? Has FDA, specifically CDER/OND, thought about adopting live minutes, similar to what currently occurs in The Office of Oncological Diseases?	Diseases (ODO). Currently CDER/OND is not considering standardizing creating live meeting minutes across divisions.
Is FDA considering transcription as a means to improve the efficiency of generating meeting minutes?	Zoom can transcribe the audio of a meeting or webinar that is recorded to the cloud. This option must be manually turned on by meeting staff. FDA policy prohibits audio or visual recording of discussions at meetings. *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products Guidance for Industry (September 2023)*

In-Person/Virtual F2F Questions*	Answers
Some divisions have different practices (e.g., only WRO for pre-IND) and this lack of consistency creates challenges. Is there a way to standardize this?	FDA described that there are usually reasons behind these differences, and every division has their own practices, which may depend on indications, familiarity with the company, differences in the drug process. These factors may make a division lean more towards a WRO, which would be difficult (and perhaps not productive/worthwhile) to standardize across divisions. FDA can aim to be more consistent, but it would not be possible to have a single standard practice across all groups. CDER and CBER are also organized differently; CBER is organized by product, whereas CDER/OND is organized by indication. *Answered live during the workshop* While there are different practices among divisions, FDA is continually working to identify areas where they can standardize processes.
For virtual face-to-face and in-person face-to-face, does FDA prefer to have a presentation or is it a good practice to have a presentation?	Presentations by requesters are usually unnecessary because the information necessary for review and discussion should be part of the meeting package, and FDA reviewers thoroughly review the meeting package. If a requester plans to make a presentation, the presentation materials should be provided ahead of the meeting. All presentations should be kept brief to maximize the time available for discussion. The length of the meeting will not be increased to accommodate a presentation. If a presentation contains more than a small amount of content distinct from clarifications or explanations of previous data and that were not included in the original meeting package submitted for review, FDA staff may not be able to provide commentary.

	Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products Guidance for Industry (September 2023)
Please clarify/restate what the maximum number of in-person attendees is now (total FDA + sponsor)?	FDA noted that the capacity limits have been increased since the initial return to in-person meetings and are at this point only limited by the number of chairs in the room. They noted that the recommendation to limit in-person attendees to core participants (i.e., those with a primary speaking role) has helped to focus the discussion while still allowing virtual attendees to listen. *Answered live during the workshop*
Will FDA restrict and let the sponsor know who from the list of attendees can attend in-person?	Anyone who is invited from FDA or Industry can attend in-person if they prefer. However, FDA recommends that for in-person hybrid meetings "observers" (those not expected or likely to directly participate in the discussion) join the meeting virtually. This recommendation is intended to enable the best possible experience (sound and video) for those joining remotely to observe the meeting discussion. In addition, HHS policy requires that all visits involving Foreign Visitors to the White Oak Campus be approved in advance by an FDA or HHS Security Official. *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products Guidance for Industry (September 2023)*
At an in-person face-to-face meeting, can attendees bring a laptop? What are some best practices that sponsors should know?	Yes, attendees may bring a laptop and connect to FDA's guest Wi-Fi. Any documents for display/presentation should be sent to the RPM ahead of the meeting as attendees may not physically connect to FDA resources.

Type D and INTERACT Questions*	**Answers**
Do multiple product/indications as a reason to deny INTERACT meetings hold true for other meeting types?	FDA typically grants a meeting for a single product development program for any meeting type, not just INTERACT. Different indications and products could have different safety profiles, clinical considerations, manufacturing challenges, etc. Typically, it would be challenging for FDA to provide targeted feedback for multiple products/indications in one meeting.
Do you think that INTERACT meeting might be denied in case proof of concept (PoC) results in animals are still not available?	Questions related to the design of proof-of-concept studies in animals to support administration of an investigational product in a first-in-human clinical trial are within scope for INTERACT. The review division evaluates each meeting request to decide if it will be granted or denied. *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products Guidance for Industry (September 2023)*

For CBER Type D, there is an understanding that briefing package should be 20-25 pages, is this accurate?	Meeting packages should provide adequate background for the question being asked. CBER does not have a policy on page counts for Type D briefing packages. Please see SOPP 8101.1: Regulatory Meetings with Sponsors and Applicants for Drugs and Biological Products
At the time of Type D submission, should we prepare the Meeting Request and Meeting Package as two separate documents and submit together at the same time? Or is it possible to submit only the Meeting Package?	Type D meeting submissions must include a meeting package with the meeting request.

Other Questions*	Answers
Where is supervisory information located which is accessible to industry?	For CDER, the RPM's chief is listed in the OND Office and Division Contact Info document on FDA's public website. CBER leadership are listed here Center for Biologics Evaluation and Research | FDA. CBER's Office of Therapeutic Products (OTP) has a common email inbox for RPMs[1], and any emails sent there from sponsors will go to all leadership in project management. *Answered live during the workshop*
With the new Diversity Action Plan guidance, which type of meeting should be requested as feedback from the Agency is not guaranteed?	Per the Guidance, FDA recommends submission of the Diversity Action Plan when a sponsor is seeking feedback regarding the applicable clinical study for the drug (typically at the End-Of-Phase 2 meeting). *Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies Draft Guidance for Industry (June 2024)*
This question is in relation to Project Optimus, what type of meeting should be requested if the intermediate Phase I data has been analyzed/available, the End of Phase I (EOPhI) has not yet been achieved, and the sponsor would like to align with the FDA on the RP2 dose(s)? The number of questions is limited to 1-2. Should this be Type C or Type D meeting request?	If you have a product specific question about meeting with the FDA, reach out to your RPM for guidance on how to proceed.
For a program with accelerated timelines and having a seamless single registrational trial with no pause between phase 1/2 and	

[1] OTPRPMS@fda.hhs.gov

pivotal, what is the best time for a EOP2 meeting?	
Would the Agency share their experience with holding Sponsor meetings such as PSA for pediatric program that Sponsor aims to harmonize very early in the development on multiple disciplines such as juvenile studies, CMC requirements and clinical, where there is not enough background or data available for the discussions. Does the Agency have any specific requirements or guidance for submitting such a meeting request from the Sponsor?	
Is there any chance that the Agency would publish guidance on "business pipeline meetings?" Perhaps a PDUFA VIII proposal?	Thank you for this comment and idea. We'll review all public comments and ideas ahead of the next round of PDUFA negotiations.
Is FDA considering mechanisms to provide transparency to sponsors about if and when a document will be reviewed?	

* Some questions have been edited for clarity.