October 20, 2025

BIO WHITE PAPER ON MANAGING FDA/INDUSTRY MEETINGS

I. Introduction

Meetings between the Food and Drug Administration (FDA) and industry sponsors are critical to conducting effective and efficient drug development and bringing life-changing, innovative medicines to patients. Industry sponsors, FDA, and Congress have recognized that timely interactive communication between the Agency and sponsors during drug development is a core Agency activity.[1] These interactions, beginning with the pre-IND phase, help to ensure that sponsors can prepare and submit complete NDAs and BLAs. During the review period, early identification and resolution of issues helps to support first-cycle approvals, conserving Agency and industry resources that would otherwise be consumed by multiple review cycles. Interaction through meetings is particularly important for innovative products or use of innovative approaches for which development can be impeded by uncertainty regarding FDA's expectations.

The purpose of this White Paper is to highlight the importance of timely, substantive, and collaborative communication through well-constructed interactions between sponsors and FDA during drug development and the review process. It highlights best practices for sponsors and FDA for meeting-based interactions that ultimately lead to enhanced public health.

II. Background

A. Prescription Drug User Fee Act (PDUFA) Meetings Goals

The importance of FDA/sponsor interactions through meetings was recognized and addressed early in the PDUFA program. In the second iteration of PDUFA,[2] industry and FDA recognized that devoting resources to meetings was crucial to improving the efficiency and outcomes of the review process, and FDA committed to certain meeting management goals as part of the fee-supported package. The goals included timeframes for responding to sponsor requests for meetings, scheduling and holding different types of meetings, and preparing meeting minutes to capture the substance of what was discussed. During the subsequent five reauthorizations of PDUFA, industry provided additional resources to FDA to tighten the goals and add new categories of meetings to the commitments. (Figure 1)

[1] PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027 (PDUFA VII Commitment Letter), Section I.K.1, at 27.
[2] Food and Drug Administration Modernization Act, Pub Law 105-115, November 21, 1997; PDUFA Reauthorization Performance Goals and Procedures, 1997.

In addition, under PDUFA VII, FDA committed to hold a public workshop to discuss best practices for meeting management,[3] and it held the Public Workshop on July 22, 2024. During the Workshop, FDA presented statistics on the number and types of meetings held, and FDA's performance in meeting the goals. Notably, in FY 23,[4] FDA held over 4,000 PDUFA formal meetings.[5] However, in FY 23, FDA only met 6 of 14 meeting performance goals from the PDUFA VII Commitment Letter. (FDA reported in the final FY 23 data that they met 11 or 22 meeting management goals.[6]) FDA staff presenting at the workshop observed that in several cases the goals were only missed by a few percentage points, and the trend was positive towards meeting more of the goals in future years, but industry remains concerned that the goals are not being met despite the resources provided under PDUFA.

FIGURE 1
NOTABLE CHANGES DURING PDUFA REAUTHORIZATIONS

- **PDUFA III** added a 21-day timeline for responding to Type B and Type C requests (Type A remained at 14 days)
- **PDUFA V** added the written response only ("WRO") meeting format for Pre-IND ("Type B") and Type C
- **PDUFA VI** established unique timelines for Type B End-of-Phase ("EOP") meetings
- **PDUFA VII** established Type D and INTERACT meetings; modified WRO eligibility

Source: Public Workshop Slide 13

B. The Role of Regulations and Guidance in the Drug Development and Review Process

The meetings that FDA conducts with sponsors are essential for addressing unique aspects of a specific drug development program. Guidance and regulations complement meetings and allow FDA to document expectations for drug development and the contents of NDAs and BLAs in a way that broadly covers many aspects of the development and review process, such as FDA's expectations for non-clinical development programs, clinical trial design, chemistry, manufacturing, and controls, and labeling. These are developed with FDA's unique knowledge gained from the thousands of product specific meetings and reviews of INDs, NDAs, and BLAs and allows for public comments on the principles FDA is laying out. This public comment process is a vital interaction that must be maintained, allowing stakeholders to engage with and

[3] PDUFA VII Commitment Letter, Section I.K.1.a. says, "FDA will hold a public meeting to discuss best practices for meeting management by July 30, 2024, including issues related to submission of meeting requests, efficient time management, coordinating meeting agenda, development and submission of meeting background packages and lessons learned from the Coronavirus Disease 2019 ("COVID-19") pandemic including virtual meeting platforms. Learnings from the public meeting could inform FDA's internal process improvement efforts and, as appropriate, be reflected in updating guidances…"
[4] FY 2023 ran from October 1, 2022 to September 30, 2023.
[5] FDA, PDUFA VII Public Workshop for Meeting Management Best Practices Slides, Slide 15. See also, Public Workshop on Meeting Management Best Practices, July 22, 2024, AI Generated Transcript (Workshop Transcript), at 72. The Workshop Transcript is unpaginated. References are to the numbered paragraphs in the transcript. FDA also published a summary of the public workshop prepared by the Eastern Research Group which is available at https://www.fda.gov/media/181396/download?attachment (accessed May 14, 2024).
[6] FDA-TRACK: Prescription Drug User Fee Act Meeting Management | FDA

shape proposed policies, ensuring that regulatory approaches reflect real-world considerations and evolving scientific perspectives.

One of the primary goals of FDA guidance is to provide sponsors with clear expectations for drug development, thereby reducing the number and complexity of product-specific meetings. When guidances are comprehensive and up to date, sponsors can more confidently design their programs in alignment with current FDA expectations while potentially reducing the need for program-level clarification. Industry continues to support the development of guidance documents by providing resources through the PDUFA program, as they not only promote consistency and efficiency but also provide a formal mechanism for sponsor feedback and a shared understanding between FDA and stakeholders. While these documents are a necessary foundation, they are not intended to replace the function of direct interactions between sponsors and FDA to address situations beyond the recommendations of published guidances.

C. FDA/Sponsor Meetings Are Critical Interactions Necessary for Success

Because regulations and guidance are necessarily broad and designed to cover a wide variety of issues across many different types of drug development programs, it is important that they are paired with meetings that can address questions that pertain to a specific novel drug development program. Interactions between industry and FDA review teams to address specific drug development questions are critical to success. Resources provided through PDUFA are intended to ensure that the review divisions are fully staffed to support these interactions. PDUFA resources also support FDA policy staff who, in addition to the substantive regulations and guidance described earlier, also produce procedural guidance on how to best plan for and conduct these interactions to make them more productive and reduce the need for follow up. These staff are also frequently consulted by review teams to help interpret and implement policy within specific applications, making them an integral part of the review process as well as policy development.

In the discussion that follows, this paper outlines best practices for FDA and sponsors in conducting efficient and effective meetings. Although the focus is on formal PDUFA meetings, many of these practices are also applicable to other types of interactions not covered by PDUFA.

III. Best Practices for Conducting Efficient and Effective FDA/Sponsor Meetings

FDA has issued a Draft Guidance, *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products Guidance for Industry* (Meetings Guidance).[7] The Meetings Guidance discusses the various formal meeting types under PDUFA and how to submit meeting requests and prepare for, schedule, conduct, and document the meetings. Even though it is currently designated as a "Draft Guidance", all sponsors should consider it a primary reference when requesting a meeting with FDA.

A. Meeting Requests and Preliminary Feedback

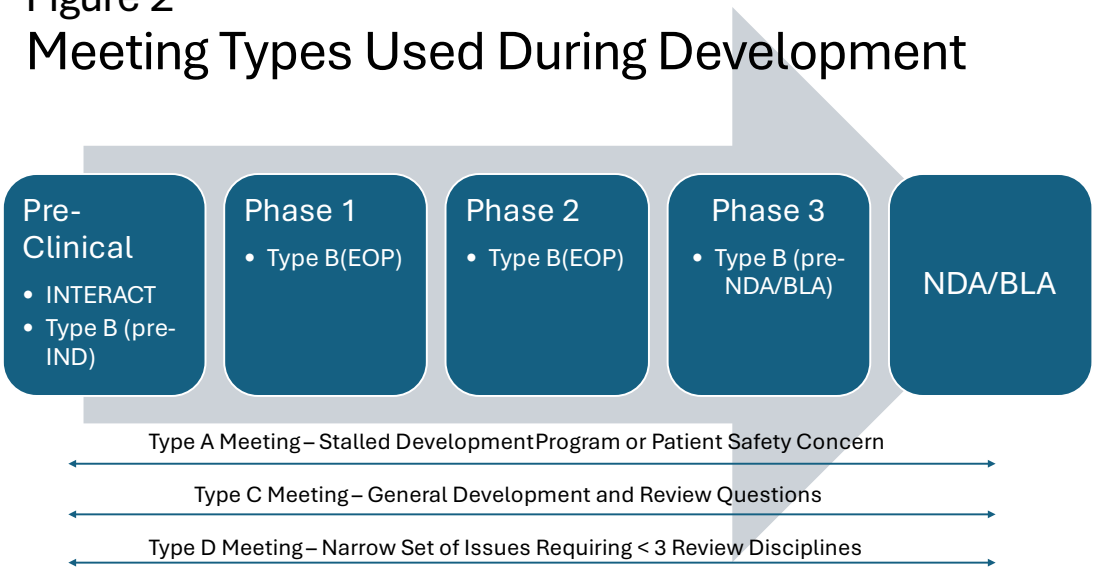
[7] FDA *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products Guidance for Industry*, Draft Guidance, September 2023. https://www.fda.gov/media/172311/download accessed May 2, 2025.

1. Sponsor Best Practices

a. Request meetings of the appropriate type and at the appropriate times

Before requesting a meeting, sponsor preparation is critical. Sponsors should familiarize themselves with the types of available meetings and the timing associated with each in order to request the right type of meeting (Figure 2).[8] When deciding at what point(s) to request a meeting, note that although early input from FDA is most helpful when shaping a development program, sponsors should acknowledge the risk that any advice provided by FDA might change as the program takes shape. Sponsors generally should view meetings as opportunities for continuous collaboration and dialogue with FDA rather than just for obtaining answers to specific questions. In addition, when preparing for a meeting on a particular issue, sponsors should consult FDA guidance and regulations that might touch on the issues and consider FDA's expectations as described in any applicable guidance or regulation. FDA may reject meeting requests if the questions to be posed during the meeting are already covered by a guidance or regulation.

Figure 2
Meeting Types Used During Development



b. Choose the appropriate meeting format

Once a decision is made to request a meeting, the sponsor must decide which format of meeting to request. FDA offers four meeting formats, although only the first three are actually meetings:[9]

[8] *Id.* at 2-5 (Section 3).
[9] Meetings Guidance at 6.

- In person, face-to-face
- Virtual face-to-face (video conference)
- Teleconference (audio only, by telephone or virtual meeting program, cameras off)
- Written Response Only (WRO)

Sponsors should consider the questions they have for FDA and carefully assess their preferred format for the engagement. If the sponsor prefers to have a face-to-face meeting, framing the questions appropriately can influence whether their request will be granted. Questions should reflect a strong understanding of the meeting purpose, be specific with clear intent, and take into account the existing regulatory framework. If a sponsor requests an in-person face-to-face meeting, FDA has indicated that it would appreciate an explanation for why an in-person rather than a virtual meeting is preferred.[10] Such an explanation might influence FDA's decision on whether to grant the request or convert it to a virtual format or WRO. FDA has also indicated that having the briefing book with the meeting request can help make the decision whether to grant the format of meeting that is requested or convert the request to a WRO.[11]

If there are only a few questions to be discussed or for less critical meetings, virtual face-to-face meetings can save time and expense. Ideally, for a virtual face-to-face meeting, all sponsor participants will either be in a central location or have a separate platform to communicate during the meeting. Given the capabilities of modern video platforms, sponsors are encouraged to choose videoconferencing over teleconferencing whenever possible, as video allows for the observation of facial expressions and body language, which can provide important context, improve mutual understanding, and enhance the overall effectiveness of the meeting.

While a Written Response Only (WRO) format may not be the preferred default option for sponsors to receive feedback on a complex question, it can be effective for addressing straightforward questions that do not require back-and-forth dialogue. Sponsors may request a WRO outright, and FDA may also convert a meeting request to a WRO if it determines that written feedback is the most appropriate path forward, though it typically does not provide a detailed explanation for doing so (see Section A.2.b under FDA Best Practices). Because WROs place less burden on FDA resources, sponsors are encouraged to consider them when appropriate. However, when WRO responses are unclear, off-target, or miss the intent of a question, the lack of opportunity for real-time clarification can be frustrating. Face-to-face meetings are more likely to provide opportunities to probe FDA's thinking on relevant issues and obtain valuable insight into programmatic challenges.

c. Get to know your Regulatory Project Managers

For sponsors, the Regulatory Project Manager (RPM) assigned to an investigational new drug application (IND) or NDA or BLA is perhaps the most important FDA contact with regard to a drug development program and an application. A sponsor beginning a drug development program should contact Chief Project Management Staff (CPMS) in the relevant review division, the Director of Project Management Staff (DPMS) in the relevant office, or the Director of the

[10] Workshop Transcript at 336.
[11] *Id*. at 534-37.

Office of Regulatory Operations (ORO) to determine which RPM will be assigned to the project. A list of the DPMSs and CPMSs for each office and review division can be found on FDA's website.[12]

Communication with the RPM should be bidirectional. To build the relationship, sponsors should alert RPMs to upcoming meeting requests and other important IND submissions. They will appreciate the advanced notice on these developments and be better prepared to address them in a timely manner.

A responsive RPM can provide timely advice and ensure that the sponsor's interactions with FDA are both efficient and productive. Having open dialogue with the RPM enables collaboration between the sponsor and FDA that facilitates meeting engagement. In this context, RPMs should be able to provide at least the following assistance:

- Advise sponsor on appropriate meeting type or other recommended approach for obtaining FDA's advice, as not all interactions need to fall under a formal meeting type
- Ensure availability of key FDA attendees at a meeting, including attendees from multiple divisions for cross-indication topics for a given product
- Assist in structuring the meeting agenda
- Address procedural questions
- Provide possible date(s) for receipt of FDA's preliminary comments
- Collaborate with sponsor on an efficient way of engaging with FDA on a particular issue
- Follow up with FDA staff and internal committees to obtain clarification responses requested by the sponsor

PDUFA commitment letters have acknowledged the need for a well-staffed FDA. Having enough RPMs is important to that effort as short staffing could result in delays in follow-up. If, after a reasonable amount of time, sponsors are unable to connect with the assigned RPM, FDA recommends the sponsor reach out to the CPMS or the DPMS and let them know.[13]

d. Prepare meeting requests and background packages

When a sponsor requests a formal meeting with FDA, the sponsor must submit a written request to FDA.[14] The Meetings Guidance contains detailed information about the format and content of meeting requests.[15] If elements of the meeting request are omitted, FDA could reject the request, so it is essential that the meeting request be carefully prepared.

Notably, a request should include a list of proposed questions, grouped by FDA discipline, including a brief explanation of the context and purpose of each question.[16] Devising the questions requires knowledge of existing relevant guidance, the status of the development program and pending issues, and strategic thinking to make the most of the meeting. While the

[12] https://www.fda.gov/media/78312/download?attachment (accessed May 7, 2025).
[13] Workshop Transcript at 411-14.
[14] Meetings Guidance at 7.
[15] *Id.*
[16] *Id.* at 8-9.

use of simple "yes" or "no" questions should be considered carefully, they are not inherently problematic, particularly when seeking FDA's agreement with a proposed approach. That said, when sponsors would like to avoid a WRO, it is important to frame questions in a way that invites dialogue and highlights the rationale behind the request. Questions should provide sufficient context and indicate clearly where discussion is sought, rather than suggesting a closed-ended response would suffice. Sponsors may also consider signaling in the meeting request which questions are intended for discussion, and which are appropriate for written response. In some cases, what appears to be a "yes" or "no" question is preceded by detailed explanation, and FDA's response often includes clarifying context rather than a binary answer.

FDA recommends having a reasonable number of questions—no more than ten—that can be discussed in a one or one and a half hour meeting.[17] These questions generally should not be changed after they are submitted as it can disrupt FDA activities associated with developing responses to questions, particularly if it involves a discipline not previously included in the internal discussion of the meeting request.

The proposed agenda, a required component of the meeting request, should be carefully crafted so that adequate time is allotted to the highest priority questions, with time provided for discussion. Sponsors should determine who will be the lead for each topic on the agenda and the speakers who will present. FDA has recommended that sponsors not take up too much time with presentations from patient advocates and principal investigators.[18] Although FDA is happy to hear from such groups, the primary purpose of the meeting is to discuss the sponsor's drug development program and provide responses to the questions. If such advocates are to be included, FDA recommends they participate in the second half of the meeting.[19]

Sponsors also are expected to prepare and submit a meeting package at the time of the request for Type A, D, and INTERACT meetings, and certain Type C meetings.[20] Meeting packages for Type B and other Type C meetings are due between 30 and 50 days before the scheduled date of the meeting or the WRO response time, depending on the type of meeting.[21] Timelines for submitting meeting packages should be reviewed in advance of the meeting, and meeting packages should be submitted ahead of the deadline, if available, to provide more time for the review division to prepare for the meeting.

The meeting package should be drafted prior to the meeting request and undergo robust review internally to ensure questions are well thought through and that the briefing document contents are high quality. For this reason, it is best to prepare the package along with the meeting request, even if the package is not due to FDA until later in the process. The meeting package should be succinct yet sufficiently detailed to enable FDA to fully understand and respond to the questions

[17] *Id*. at 9. The Meetings Guidance requests that sponsors not submit subquestions; if submitted, subquestions will be counted as full questions. Meetings Guidance at 9.
[18] Workshop Transcript at 474-81.
[19] *Id*.
[20] Meeting packages must be submitted with the request for Type C meetings that are requested as early consultations on the use of a new surrogate endpoint to be used for product approval in a proposed context of use, meetings. Meetings Guidance at 12.
[21] *Id.*

posed. While it is important to include relevant context and supporting information, sponsors should avoid including background material simply for the sake of completeness.

e. Effectively manage preliminary feedback and WROs

As the first indication of FDA's position on the questions posed by sponsors, well-constructed preliminary responses are very important. They can be used to tailor the agenda for the meeting so that time is spent on the most complex, outstanding issues, or those most in need of clarification. Sponsors should ensure that necessary subject matter experts carefully review the preliminary responses and identify the topics that need additional discussion in the meeting. Even if most of the sponsor's issues have been addressed in the preliminary comments, if any questions remain, it may be better to retain the meeting to get them resolved, as there may not be another opportunity for follow-up. For those issues meriting discussion at the meeting, sponsors should consider what FDA is trying to convey in its preliminary responses and be prepared to clarify their position at the meeting, potentially facilitating a path forward on areas of disagreement. This is not the time for new proposals which can derail the meeting. It is, however, an opportunity for the sponsor to reexamine and align priorities internally and reach agreement on updated messaging, if warranted.

If the preliminary written responses are satisfactory, a sponsor can cancel the meeting or consider particular questions resolved, reserving upcoming meeting time for remaining complex issues that would benefit from a dialogue with FDA. However, sponsors should be very judicious in cancelling meetings based on preliminary responses.

If a request for a face-to-face meeting was converted to a WRO by FDA, the quality of FDA's written responses take on even greater importance. If FDA has converted the request for a meeting to a WRO and the sponsor disagrees with the decision, the sponsor can submit correspondence to the division, explaining its rationale for holding a meeting with a request to reconsider the meeting format. The Meetings Guidance says that FDA will consider the follow-up correspondence and may or may not convert the WRO back to the requested format. FDA should consider formalizing an opportunity for sponsors to reverse FDA's initial decision to convert a face-to-face meeting request to a WRO with appropriate rationale and justification. In many circumstances, workload for both FDA and sponsors increases when WROs lead to the need for additional rounds of dialogue and clarification. Face-to-face meetings could reduce administrative burden for all parties in these cases.

2. FDA Best Practices

a. Meeting Participants

Availability of key FDA staff is a critical determinant of the value of a proposed meeting. RPMs should be transparent about the availability of FDA personnel prior to granting a requested meeting so that sponsors can make an informed choice about whether to pursue a meeting request, seek an alternative, and manage internal expectations. If certain FDA disciplines that the sponsor requested cannot participate despite reasonable efforts, the RPM should provide an

explanation and discuss with the sponsor ahead of the meeting. Attendees for sponsors may be travelling from around the world, and there may be limited availability to have the right attendees. A timely FDA response and more detailed information from FDA can help ensure proper decision-making on behalf of sponsors. To promote more predictable interactions between RPMs and sponsors, FDA should establish guidelines and processes for RPMs in these communications with sponsors.

To ensure consistent and aligned feedback from FDA to the sponsor, it is critical that FDA include any groups or individuals that need to provide input for a meeting in all meeting activities, even if those stakeholders represent different divisions within the Agency. All FDA stakeholders should take part in preparing preliminary responses, attending the meeting, and preparing the meeting minutes. FDA should also identify the staff and disciplines involved in developing preliminary or written responses (e.g., WROs).

For face-to-face and virtual meetings, attendees from FDA are known to the sponsor and formally documented in the meeting minutes. However, when FDA provides a WRO, similar visibility into which subject matter experts contributed to the response is not currently included. Given that WROs are a formal meeting type and can serve as the only interaction on critical development issues, FDA should ensure consistent transparency by identifying individuals who contributed to the feedback. This would help sponsors better interpret the feedback, ensure accountability, and reinforce the equivalency of WROs within the broader meeting framework.

For important milestone meetings, participation and attendance of senior Division (and potentially Office level) leaders is important to ensure that the feedback from the review team reflects the views of management so that it is less likely to change during the review process. Increased involvement of senior leaders will help avoid disconnects/misalignments within the Agency, which can affect development timelines.

When FDA grants a meeting request, it should proactively provide the current titles of all attendees, their function (e.g., lead CMC reviewer), and the role they will play in the meeting (e.g., decision-maker, observer). Currently, sponsors must request this after receiving the list of attendees or try to ascertain this information independently, which is inefficient.

b. Conversion of Meeting Requests

If FDA converts a live meeting request to another type of meeting or to a WRO, FDA should provide sponsors with a clear rationale, and the sponsor should be permitted to request FDA reconsideration of the decision. In many cases, FDA simply says that it has determined that another meeting type or written response to the questions would be most appropriate. However, more detailed explanations would help sponsors understand the reasoning and adapt approaches in the future to reflect FDA's thinking.

We note that in July 2024, CBER updated their SOPP on Regulatory Meetings with Sponsors, including the Appendix D "Considerations for Meetings vs Written Response Only (WRO) for PDUFA Meetings." Although this document is a process document intended for a subset of FDA staff, the information is helpful for sponsors when considering meeting requests. Consistency

between Divisions, Offices and Centers in granting or denying meeting requests or converting them to WROs is desirable. However, FDA should continue to work with sponsors to evaluate requests on a case-by-case basis and retain the flexibility to conduct live interactions when necessary.

Conversions to another type of meeting or to a WRO seem particularly prevalent regarding the newest types of meetings-- Type D and INTERACT meetings-- as highlighted by data presented at the 2024 Workshop. Understanding FDA's thinking about why it grants or denies a meeting or converts it to a WRO would be particularly helpful for these types of meetings to enable sponsors to frame their meeting requests appropriately and increase efficiency for both parties. If trends in these data can be identified, it could be instructive to communicate them more broadly (e.g., through a Q&A document or FDA's website). Additional guidance specifically focused on the suitability of topics for Type D meetings would be particularly helpful.

c. Denials and cancellations of meetings

If FDA denies a meeting request, the Agency should provide advice on an alternative path forward. Separately, FDA should clarify if and when there is opportunity for follow-up clarification if a sponsor cancels a requested meeting after receiving satisfactory feedback via FDA's preliminary comments.

d. Providing pre-meeting feedback

For efficient meeting management, FDA should provide preliminary comments sufficiently in advance of the meeting to allow adequate time for the sponsor to consider the comments and decide whether to go forward with the meeting or narrow its scope. Generally, FDA has been providing preliminary comments up to 5 days before meetings (in line with the PDUFA commitments), which allows for better sponsor preparation.

Preliminary responses should be as clear as possible, avoiding ambiguity. Potential differences in interpretation between sponsors and the Agency can lead to disagreements during the meeting. or if the meeting is cancelled based on the preliminary responses, a drug development program can go down the wrong path leading to a deficient application.

When FDA has questions for sponsors that may require further discussion, these should be made clear in the preliminary response document so the sponsor can address them prior to the meeting, when feasible. And if FDA identifies issues in the meeting request or briefing package that are not directly related to the posed questions, FDA should provide perspectives on these issues as such information is appreciated by sponsors and can help to prevent development delays.

e. FDA-initiated meetings

Sometimes, FDA may request a meeting. In such cases, to ensure the appropriate people from the company are present and prepared for the discussion, FDA should clearly articulate the purpose of the meeting. FDA-initiated informal meetings or teleconferences on narrow topics can be particularly helpful.

B. Conducting Efficient and Effective Meetings

1. Sponsor Best Practices

For in-person meetings, the meeting team should arrive at the FDA White Oak campus well in advance of the meeting, allowing ample time to pass through security. Meeting participants should bring appropriate identification and minimize accompanying luggage.

Sponsors should select effective speakers and determine who will be the lead for each topic. It is imperative that sponsor participants speak with one voice. Differences of opinion should be discussed and resolved in advance. Preparation for the meeting should also include anticipating various scenarios and questions that may arise during the meeting and planning responses.

If FDA provides a negative response during the meeting, it is not advisable to bring up a new proposal on the spot, as FDA will likely not be in a position to vet it in real time. It would, however, be good practice to make sure that FDA's concerns are clearly understood and discuss how FDA wants to handle a new proposal. Visual aids, including slides, can be beneficial. The slide deck should contain the key information that FDA should take away from the meeting and be sufficiently clear that it can serve as a useful reference document after the meeting. If slides or other visual aids will be used, the sponsor should work with the RPM to ensure appropriate equipment is available to display them.

2. FDA Best Practices

Starting a meeting late can lead to an incomplete discussion where all agenda topics and questions might not be covered. To maximize the time for in-person face-to-face meetings, FDA should be attentive to the logistics of greeting and escorting sponsors to the room, as well as ensuring that the meeting room is available well ahead of the meeting start time. During videoconferences, all cameras should be on to enhance the interaction. FDA has said that CDER's and CBER's policy is to have cameras on, but there may be exceptions. FDA should take steps to reinforce this policy.

The objective of the meeting should be to provide sponsors with clear guidance on the path forward for the development program. As discussed previously, the involvement of Division and Office-level leadership is helpful in milestone meetings, and when FDA participants in the meeting speak with one voice, the sponsor is more likely to obtain clear guidance. If disagreements surface during the Agency's internal preparation for the meeting and cannot be resolved, they should be flagged in the preliminary responses and during the meeting so the sponsor understands the areas of disagreement and uncertainty and can provide additional information that could help to resolve the issues.

While FDA's Meetings Guidance states that sponsor presentations are usually unnecessary because all information needed for discussion should be included in the meeting package, sponsors sometimes find that additional documents (e.g., clarifying visuals or supporting data)

can help explain an issue more effectively during the meeting[22]. FDA should allow some flexibility for sponsors to reference such materials during the discussion, provided they are directly related to the pre-submitted questions and content. However, this flexibility should not be interpreted as permission to introduce new topics, present substantial new data, or shift the focus of the meeting. For meetings to be efficient and productive, it is essential that the background package be treated similarly to an application, it must be complete at the time of submission. Any use of supplemental materials during a meeting should be rare, limited to clarification, and handled transparently in consultation with the RPM.

At the end of a meeting, FDA and sponsors should take time to orally summarize the discussion and confirm agreements and disagreements and anything FDA has asked the sponsor to provide to ensure mutual understanding and expedite meeting minutes. This also provides the opportunity for the sponsor or FDA to ask a few clarifying questions to ensure complete understanding of each other's position. Alternatively, participants may consider summarizing the discussion at the end of each topic to ensure clarity for both parties. Some divisions provide real-time summaries of the conversation on the screen as a videoconference meeting progresses. This can be helpful and should be standardized across Divisions and Offices, but care must be taken to ensure that presenting live minutes does not distract from the substantive discussion.[23]

C. Post-Meeting Actions

1. Sponsor Best Practices

a. Meeting Minutes

The importance of accurately documenting the meeting outcomes, agreements, disagreements and action items in the meeting minutes cannot be over-emphasized. The minutes provide the official record of what transpired and may be referred to years later should disputes arise. Over the years-long period of drug development and review, personnel and policies may change, and it is important to have an accurate, contemporaneous record of what was said and agreed upon at meetings.

Providing sponsor-generated minutes to FDA before the official minutes of the meeting are developed can help ensure that the sponsor's understanding of the agreements at the meeting is reflected in the official minutes. This should happen within 10 days of the meeting to enable FDA to consider the sponsor input before drafting and clearing the minutes within the 30-day window.

If the sponsor identifies a significant area of disagreement with the final minutes, the Meetings Guidance recommends contacting the FDA RPM.[24] If after contacting the RPM there are still significant disagreements, the sponsor can submit a description of the disagreements either to the application, or if there is no application, in a letter to the division director with a copy to the RPM

[22] Meetings Guidance at 16.
[23] Workshop Transcript at 625.
[24] Meetings Guidance at 17.

b. Requests for Clarification

In accordance with PDUFA VII commitments, to ensure the sponsor's understanding of FDA feedback, sponsors have the opportunity to submit clarifying questions after a meeting or WRO, or after preliminary responses are provided if a meeting is cancelled.[25] FDA must respond in writing within 20 calendar days of receipt of the clarifying questions. Sometimes, new questions arise between the cycles of formal meetings or after the 20-day mark following the receipt of WRO or meeting minutes. When this happens, sponsors should talk to the RPM to determine the best path forward to resolve the questions.

2. FDA Best Practices

a. Meeting minutes

As noted above, the minutes should clearly delineate areas of agreement and disagreement, along with action items and any new information the sponsor is expected to provide. The minutes should indicate whether any requested information is required or just recommended, particularly if it involves additional data collection or analysis.[26] Finally, FDA should consider any sponsor-provided draft minutes and discuss with the sponsor's representative any areas of disagreement between the two sets of draft minutes. If the areas of agreement and disagreement and action items are summarized during the meeting, such disagreements should be rare.

IV. Conclusion

FDA and sponsors participate in more than 4,000 formal PDUFA meetings annually. Productive meetings are essential to the effective and efficient development and approval of safe and effective medicines. For innovative products or for the use of innovative approaches to data collection where there is little regulatory precedent or guidance, live interaction with FDA is particularly important to avoid delays. This White Paper has described some best practices for both sponsors and FDA in conducting these important interactions. Although many of the best practices are in use today, improvements can always be made.

In summary, BIO recommends the following:

Sponsors should…	**FDA should…**
• Objectively select the most appropriate meeting type and format	• Provide the rationale for changing/denying a requested meeting type or format and implement internal policies that drive consistency in these decisions across FDA

[25] PDUFA VII Commitment letter, Section I.J.9.b, at 27; Meetings Guidance at 18.
[26] *Id*. at 512-13.

• Follow available guidance to ensure the meeting request contains the required information and include a reasonable number of questions given the likely meeting time	• Communicate the names and titles/roles of all FDA attendees regardless of meeting type (even for preliminary responses and WROs)
• Prepare a background package that provides the necessary data and context to support the desired discussion, while being as succinct as possible	• Provide timely, unambiguous preliminary responses to questions posed in meeting requests in order to facilitate effective meeting planning
• Thoroughly consider preliminary feedback and determine how it impacts the planned meeting	• Thoroughly explain the rationale for FDA-requested meetings
• Arrive for in person face to face meetings early and prepared	• Plan ahead for in person face to face meetings to ensure the sponsor participants are escorted to the room and the meeting starts on time; Ensure cameras are on for videoconference meetings
• Identify the most appropriate speakers and topic leads, and ensure alignment on key positions prior to the meeting; Prepare for the meeting anticipating various FDA responses and scenarios	• Ensure alignment on responses to sponsor questions prior to the meeting or be prepared to articulate areas of misalignment and needed information for resolution
• Consider the use of slides or visual aids only if they support the materials included in the background package	• Allow sponsors to use slides or visual aids if it is believed to provide effective framing for the discussion
• Provide draft meeting minutes to the RPM within 10 days of the meeting	• Orally summarize the discussion and align with the sponsor during the meeting
• Request clarification of WROs or meeting minutes within the allotted time frame	• Consider sponsor-drafted minutes when preparing official meeting minutes and finalize within 30 days of the meeting

Consistency between Review Divisions, Offices and Centers is desirable, particularly since many sponsors work with multiple FDA organizations, and dealing with different approaches to similar problems is confusing and inefficient. Additional guidance, operating procedures, and training would help to improve consistency on the part of both sponsors and FDA. Given the value of discussing our respective experiences participating in these types of meetings, FDA should consider regular opportunities for dialogue similar to the public meeting conducted in July 2024 as part of the PDUFA VII agreement.