Public Workshop on Best Practices for Meeting Management

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Public Workshop Summary

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Public Workshop Summary

Introduction and Executive Summary

Formal meetings between the pharmaceutical and biologics industry (Industry) and the U.S. Food and Drug Administration (FDA) allow for communication during drug development that provides scientific and regulatory advice prior to a sponsor's drug or biologic marketing application. In the sixth re-authorization of the Prescription Drug User Fee Act (PDUFA VII), FDA committed to continue holding meetings established in past commitments as well as establishing two new meeting types, Type D and Initial Targeted Engagement for Regulatory Advice on CDER and CBER ProducTs (INTERACT). FDA also committed to hold a public workshop with Industry to discuss best practices for meeting management. In order to fulfill this commitment, FDA contracted Eastern Research Group, Inc. (ERG) to conduct an analysis of current meeting management practices and facilitate a public workshop at FDA's White Oak Campus. The public workshop, entitled "Best Practices for Meeting Management Under PDUFA VII" took place on July 22, 2024, in Silver Spring, MD, with a virtual option available via Zoom for remote attendees.

Speakers from FDA not only presented an overview of FDA's performance on a variety of PDUFA meeting management metrics, but they also engaged in panel discussions with Industry representatives to seek and provide feedback on the current best practices for meeting management and potential areas of improvement.

The following key themes emerged from panelist discussion throughout the workshop:

1. FDA and Industry are motivated to make meetings as effective, efficient, and meaningful as possible. Meetings should be used for FDA to provide scientific and regulatory advice as necessary throughout the drug development process, and FDA and Industry should aim to collaborate and ensure any uncertainties about FDA's regulatory advice are clarified throughout the course of the meeting.
2. FDA and Industry find that virtual face-to-face meeting interactions can provide equally substantive discussion as in-person face-to-face meetings, and the virtual format is often preferable in that it allows for increased participation of long-distance attendees. In contrast, Industry suggested more standardized practices around the use of written responses, expressing a preference for a live meeting interaction (whether virtual or in-person) in instances where ambiguity may arise with written responses only (WRO) and no accompanying discussion.
3. While appropriate requests for the new meeting types (Type D and INTERACT) have increased since their inception and are facilitating beneficial communication between FDA and Industry, there remain lingering questions among sponsors about the proper timing and context of these meetings.

FDA Presentation – Overview of PDUFA Meeting Metrics

Following the opening remarks from Ms. Danielle Villata, the workshop began with a presentation from Mr. J. Paul Phillips, the Director of the Office of Program Operations within the Office of New Drugs in FDA's Center for Drug Evaluation and Research (CDER). The presentation covered the history of PDUFA meetings, in addition to detailed metrics and data on formal PDUFA meetings. This information

addressed specific PDUFA VII commitments and provided foundational knowledge and context for the panel discussions.

Mr. Phillips detailed FDA's performance trends on various user fee goals associated with formal PDUFA meetings. He also shared key metrics associated with the two new meeting types under PDUFA VII:

- **Type D**: Narrowly scoped issue(s) at key decision points.
- **INTERACT**: Novel questions and unique challenges early in development, prior to filing IND.

Mr. Phillips outlined the different meeting types, timelines, and format options FDA has to provide regulatory/scientific advice in response to sponsors' meeting questions. Mr. Phillips briefly reminded audience members of the impact of COVID-19 on FDA's meeting management practices during the Public Health Emergency (PHE), namely the necessary restriction on in-person meetings, and then detailed CDER's and CBER's phased return to in-person meetings, starting just prior to the expiration of the PHE. Mr. Phillips also pointed out that as a result of lessons learned during the PHE, and with the help of technological advancements, the Agency and Industry established the ability to conduct face-to-face meetings in either a virtual or in-person format.

For further details and complete meeting performance data, see the workshop video recording and PowerPoint presentation on the public workshop website.[1]

Panel Discussion 1 – General Purpose and Objective of FDA-Sponsor Meetings

The first panel discussion of the workshop focused on what FDA and Industry hope to achieve through meeting with one another. FDA and Industry agreed that the main objectives should be to facilitate regulatory compliance and give scientific advice to reduce regulatory uncertainty and ensure that safe and effective products become available to the public. They agreed that meetings should be timely, efficient, and collaborative, and that they should provide substantive regulatory feedback that is appropriate to the stage of development and clarifies the path forward. Questions should be focused, appropriate, and meaningful, and they should come with timely background information to facilitate a complex discussion.

The panelists also discussed the best practices for both FDA and Industry to ensure the meeting objectives are better achieved. Industry requested that FDA provide clear guidance on issues as early in development as possible so that there is sufficient time to generate and implement solutions and alternative pathways, which is crucial for Industry due to the monetary investment associated with drug development. Industry also emphasized the importance of FDA sticking to PDUFA timelines to prevent delays in development. For sponsors, the Industry panelists emphasized that it is crucial to be aware of FDA regulations, guidance, and communicated best practices to ensure that interactions are meaningful and time is not wasted. They also stated that sponsor meeting packages need to be succinct and sufficient, providing FDA with the necessary information to facilitate discussion without overburdening FDA with excessive background and data. Industry stated that they welcome FDA to take the time to speak off-camera during teleconferences or virtual face-to-face meetings to ensure concurrence and

[1] *https://www.fda.gov/drugs/news-events-human-drugs/public-workshop-best-practices-meeting-management-under-pdufa-vii-07222024*

facilitate efficient decision-making, and they appreciate when FDA provides them with the same opportunity.

The Industry panelists raised the issue of ensuring that FDA has sufficient representation of staff with decision-making authority present in the meetings themselves or providing written responses to ensure that advice comes quickly and remains consistent throughout the development process. Per follow-up questions from the FDA panelists, Industry elaborated to say that they feel as though there may have been times in which signatory-level individuals from FDA were not reviewing their packages, which led to the offering of advice that was later changed. They want to ensure that the signatory is aligned with advice the first time it is given. Industry noted that this can be particularly challenging when working with multiple divisions on interdisciplinary questions, and they want to prevent having multiple engagements to receive answers by requesting that FDA provide interdisciplinary responses in the first place, though they noted that they do not always know the correct people to invite. In response to this, FDA emphasized that it is imperative that sponsors submit well-constructed questions and clearly indicate what disciplines and information are needed to answer them in the request so that FDA can ensure an appropriate response that meaningfully fulfills the ask, includes the appropriate disciplines, and is satisfactory to all parties.

The Industry panelists requested that FDA grant the requested meeting format whenever possible, noting that a conversion to a WRO from a live meeting greatly reduces the ability for back-and-forth discussions and a collaborative process, which are crucial to gain clarity at any phase of the development process. In response to this, an FDA panelist recommended that Industry include justification in their packages surrounding why a live meeting is necessary and valuable as opposed to a written response. This would help FDA to better prioritize and allocate time. Industry stated that this advice is helpful. They added that when they receive a conversion to WRO it is confirmation that their questions were clear enough to be answered by FDA in written form, but the issue arises when the FDA response arrives and there is a question about interpretation of FDA's response. They noted that with WROs, they do not believe there is a mechanism to engage with FDA in discussion of their responses when they feel as though there are still open items. Often, they feel as though these items could be quickly cleared up if there was an opportunity for dialogue. However, FDA stated that Requests for Clarification can be used after a WRO.

Panel Discussion 2 – Meeting Requests and Background Packages

The second panel discussion of the workshop focused on the best practices for preparing and submitting meeting requests and background packages.

FDA recommended that sponsors consult publicly available information for answers to their questions before asking FDA to allow FDA to focus their time on more complex questions that are critical to drug development and which are not addressed in publicly available guidance. Industry agreed with this, reiterating the point during their comments, and stating that it is important for sponsors to be mindful of the number of questions as well. They noted that if sponsors have many questions, they can request multiple meetings to make each individual request more digestible. The Industry panelist added that the questions should not be changed by sponsors between the request and the briefing package, so sponsors should be deliberate and thoughtful in their initial requests and ensure that they are ready to meet. Industry asked whether an excess of questions could motivate a WRO conversion, and FDA

answered that while the practice may vary by division, the most common response would be to ask the sponsor to reduce the number of questions. FDA noted that it is equally challenging and time-consuming to respond to a request with over 20 questions in any format, as even with WROs they must still have internal meetings to discuss the questions, and these tend to be limited to an hour per request. FDA stated that the most manageable number of questions is 10 or fewer, as currently outlined in the draft meetings guidance, and having too many questions to respond to in a limited amount of time can impact the quality of the responses and meeting discussion.

FDA also stressed the importance of requesting an appropriate meeting type for the phase of development and ensuring that the data is available to support the request. For INTERACT meetings in particular, sponsors should be in a place where they have identified a product and indication but have not made significant progress towards manufacturing and safety studies, otherwise the request would be more appropriate for a pre-IND meeting. During their comments, Industry noted that they do continue to have some confusion regarding the most appropriate time and manner to use the new meeting types and stated that they would appreciate FDA's ongoing clarification. FDA panelist in CBER highlighted a resource titled "Interactions with Office of Therapeutic Products" that provides information about possible meetings that the sponsor may have with CBER's Office of Therapeutic Products (OTP), including information on meetings held during early stages of product development such as pre-IND and INTERACT meetings.[2]

FDA stated that questions about the appropriate meeting type can be directed to the regulatory project manager (RPM), and it is also helpful when sponsors 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). Industry noted that it can be challenging to get ahold of the RPMs and there is variability in their response times, and FDA stated that if Industry does not receive responses from RPMs within a reasonable amount of time, they may reach out to that RPM's chief, which should be listed on the division's public website. In addition, for CBER OTP, they have a common email inbox for RPMs,[3] and any emails sent there from sponsors will go to all leadership in project management.

Industry panelist commented that it is also imperative that sponsors are prepared to submit the background package within the PDUFA timeline so that FDA has enough time to review and provide meaningful feedback. One of the Industry panelists stated that they find that it is a best practice to prepare the background packages with the most critical information at the front and additional supporting reference information in appendices for FDA to reference as needed.

FDA highlighted that the background package should not be too brief nor too voluminous. Specifically, CBER panelist noted that INTERACT background packages should be about 50 pages. For other meetings the package will vary by meeting type and topic of discussion, but CBER recommends about 50-100 pages and anything over 250-300 pages is considered voluminous. CDER added that there is no page count limit for background packages submitted for CDER products. Additionally, FDA requested that sponsors specify whether they would prefer a virtual or in-person format when requesting a "face-to-face meeting" to mitigate the need for the RPM to reach out and ask.

[2] *https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/interactions-office-therapeutic-products*
[3] *OTPRPMS@fda.hhs.gov*

Post-meeting Addendum

The FDA prepared the following additional talking points related to this topic, but due to time limitations these were not discussed during the meeting:

Best practices for meeting requests and preparing/submitting a background package

- Provide multiple options for meeting dates or timeframes. Keep in mind the varying submission timelines per meeting type when requesting and submitting meeting packages.
- Requestors should include the required elements as outlined in guidance. Address the recommended elements related to your program such as combo product info, pediatric study plans, and human factors or describe why these do not apply.
- More information about meeting interactions with CBER OTP can be found on FDA's website: *OTP Pre-IND Meetings | FDA*

Best practices for questions or issues to include in a background package

- Consider grouping questions by discipline, and refrain from asking questions about fileability or approvability.

Panel Discussion 3 – Meeting Management for All Meeting Types

The third panel discussion of the workshop focused on the best practices for managing time, agendas, and meeting interactions, in addition to the trainings and/or communications related to meeting management that would be most useful in the future.

FDA described that they like to run meetings with the premise that it is the sponsor's hour to use in the manner that is most meaningful and effective for them, however they recommend prioritizing scientific and regulatory questions for the beginning of the meeting. When sponsor questions are not prioritized and time runs out sponsors are left with unanswered questions, leading to the need for another meeting request cycle. In a similar vein, FDA has found that it is a helpful practice to forgo lengthy introductions at the start of the meeting and limit presentations on material that has already been covered by the briefing book to leave more time for discussion of questions. Meeting participants can instead identify themselves the first time that they speak, and industry may assume FDA has thoroughly reviewed the background material. Industry agreed with these best practices, adding that meeting conversations are much more effective when FDA staff turn their cameras on during virtual face-to-face meetings to allow participants to see their faces and body language. Industry noted that they apply this best practice themselves. FDA noted that CBER and CDER agree with this approach for those with a primary speaking role and have communicated expectations regarding cameras on to all staff for virtual face-to-face meetings, recognizing there may be emergency exceptions. FDA also noted that teleconferences by definition are audio only, so there is no expectation for cameras to be turned on.

FDA pointed out that FDA and Industry should work together to facilitate an efficient meeting. They noted that a critical way to do this is for Industry to provide FDA with a list of the questions that they would like to focus on in advance of the meeting following their receipt of the preliminary comments. In addition, Industry should send any additional information (e.g., slides they plan to use during the

meeting discussion) in advance so FDA can be prepared. Industry echoed this sentiment during their comments, stating that it is important to use the meeting time to only focus on points that warrant further discussion. In addition, Industry stated that they try to come into meetings with alignment on key points so that they may speak in one voice, and they appreciate when FDA does the same.

On the Industry side, they noted that they find it to be a helpful practice when FDA and Industry take the time to ensure agreement on decisions and next steps so that there is no misunderstanding of expectations and timelines. Along the same lines, it is helpful to have a summary period at the end of the meeting to go over the major agreements and ensure concurrence. Industry also stated that it would be helpful to have more clarity in the language that FDA uses so they can understand when items that are stated as "suggestions" are requirements. FDA noted that they are very deliberate with their language and often use the word suggestion to show that they are providing their medical and/or scientific opinion, and they will only use "must" or "require" in reference to laws and regulations. They noted that because sponsors may have alternative approaches, they do not want to unnecessarily set requirements and stifle development and innovation.

Industry noted that they appreciate when preliminary comments are sent as early as possible, perhaps even before the PDUFA timeline, if possible, because it allows them more time to prepare for the meeting. They asked if FDA appreciated the same courtesy with briefing books and FDA responded in the affirmative, describing that early briefing books allow them to gain a better sense of the complexity of questions. FDA noted that there have been times when they receive a meeting request and the questions seem straightforward, so they convert to a WRO. However, when they receive the briefing book, they realized there was more complexity. They noted that if sponsors feel strongly that having a live meeting with FDA is necessary, it can be helpful to provide FDA with additional information detailing why. Industry added that when FDA converts the format to a WRO, it would be helpful if FDA could provide their reasoning and potentially an opportunity for dialogue so that Industry can further justify their interest in a live meeting interaction. In addition, Industry stated that it would be helpful for written responses to state more clearly which staff or disciplines contributed to the answers.

Post-meeting Addendum

Industry prepared the following additional talking points related to this topic, but due to time limitations these were not discussed during the meeting:

- An ongoing pain point has been the inconsistencies in how to navigate the who, what, and when in instances where multiple FDA stakeholders/experts are needed for meetings (e.g., COA, digital COE, combination products). When working across several divisions, sponsors continue to occasionally receive conflicting advice on the correct discipline to request the meeting from (e.g., Digital COE vs. Division, with request to invite the other party) which creates inefficiencies for both the sponsor and the agency. Above all, FDA should be clear and consistent regarding their expectations for meetings, both for sponsors and FDA staff. This can ensure predictability in meeting experiences and better implementation of how meetings are granted. Industry looks forward to an updated Best Practices for Communication Between IND Sponsors and FDA During Drug Development guidance.

Panel Discussion 4 – Meeting Minutes and Follow-Up Opportunities

The fourth panel discussion of the workshop focused on the best practices for taking, discussing, and approving meeting minutes, in addition to the best practices for follow-up clarification opportunities.

FDA described that meeting minutes should not be expected to be a transcript of the discussion, but rather will capture agreements, disagreements, decisions, and action items. They will also clearly identify any additional topics discussed in a separate, distinct section. Minutes will be discussed and approved by all necessary relevant parties at FDA prior to being released to the sponsor.

FDA noted that in order to ensure the accuracy of meeting minutes, it can be helpful to have summary moments throughout the meeting. These can occur after each question and/or topic or occur at the end of the meeting, and they should focus on capturing key decisions or agreements reached and any action items or next steps. This allows FDA and Industry to clear up any misunderstanding and ensure information is captured correctly and efficiently, which can also expedite the development and release of meeting minutes. Industry agreed that this is a helpful process and noted that it may be beneficial to deliberately carve time for it into the agenda to ensure that the time is left. FDA added that it would be helpful to have a shared understanding of how and when summarizing will occur throughout the meeting to ensure efficiency. Industry stated that the taking and sharing of live meeting minutes could facilitate the summarizing process but noted that there would need to be staff appropriately trained for this task.

FDA emphasized that it is crucial for requests for clarification to be sent prior to the 20th day after receiving the WRO or meeting minutes to be eligible for a response in 20 days. The requests should also truly be looking for clarification on topics that have already been discussed, and they are not an appropriate setting to raise new proposals or issues. Industry agreed that it is important for sponsors to be timely, though they noted the time delay involved in the formal process (up to 20 days for Industry to submit clarification request and up to 20 days for FDA to reply). They wondered whether there could be another option for smaller, more straightforward questions to facilitate faster answers. FDA stated that there is no “one size fits all” answer to this as it will always depend on the complexity of the follow-up. Some clarification requests may require multiple disciplines to respond, which will necessarily take more time, as will questions with more challenging answers. FDA noted that the current draft formal meetings guidance contains information about the follow-up opportunity, and input from this public workshop may be used to update the guidance as needed.

Industry stated that it would be helpful for FDA to amend the meeting minutes when applicable following their response to the request for clarification. FDA stated that they will only amend the meeting minutes if it is determined that key points of information were captured incorrectly, but editorial or minor edits will likely not be made. They also noted that requests for clarification will not change the meeting minutes because a separate formal written communication will be issued to the sponsor documenting the FDA clarification to the sponsor’s clarifying question(s). The clarification questions also tend not to be about the correctness of meeting minutes but rather about ensuring understanding. Issues with accuracy of meeting minutes are separate from the request for clarification through the follow-up opportunity process. Questions about accuracy should be directed to the assigned RPM.

FDA noted 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 any needed 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.

Industry stated that there are times when new questions arise between the cycles of a formal meeting or after the 20-day mark following the receipt of WRO or meeting minutes, and they would ask FDA to consider the best way to address these questions. They noted that some RPMs are open to a quick phone call or email, but it would be helpful to have a standardized process. FDA stated that if there are still items on which sponsors have a lack of clarity, they would encourage them to work with their RPM to determine the best path forward. Some divisions may prefer a more formal meeting process, whereas others may be comfortable with a quick, informal communication to answer clarifying questions.

Panel Discussion 5 – In-Person and Virtual Face-to-Face Meetings

The fifth panel discussion of the workshop focused on experiences with and best practices for both in-person face-to-face and virtual face-to-face meetings.

FDA noted that all in-person face-to-face meetings now take place with a hybrid component, and overall, the return to in-person face-to-face meetings has been a positive experience. They noted that limiting the in-person attendees to core participants helped to focus the discussion while still allowing virtual attendees to participate. Industry shared the FDA viewpoint that they generally prefer virtual face-to-face meetings and find them to be effective as long as participants turn their cameras on; however, there are still certain meetings which they believe are important to hold in-person. FDA agreed with Industry's view and noted that communications have been sent to staff to standardize expectations for cameras to be on during virtual meetings. FDA also noted that a hybrid component had been added to in-person meetings to allow individuals without speaking roles from both Industry and FDA to attend for awareness. Industry stated that it can be challenging to select in-person participants when the numbers are limited, but FDA clarified that there are no limits on in-person attendees other than the practical constraints of room capacities; FDA's recommendation is to have individuals with a primary speaking role attend in-person.

FDA emphasized that it is important to identify in-person foreign national attendees without a US passport because there is an HHS clearance process that has to take place, in addition to specific ways that they will need to navigate security on FDA's campus. All attendees should arrive to the FDA campus on-time to navigate security and travel to the conference room, and they should contact their on-campus escort immediately if any issues arise.

FDA detailed that while there were initially technology challenges early in the PHE associated with virtual face-to-face meetings, their experience is that everyone adapted to the process and the format now allows for meaningful discussion. The virtual meeting format enables FDA to utilize internal chats to privately discuss sponsor proposals during the meeting and reach concurrence, which allows Industry to receive more answers to their questions in a timely manner. The virtual space has also alleviated previous scheduling issues associated with FDA staff competing for a limited number of conference rooms at the White Oak campus. Industry agreed that virtual face-to-face meetings are very successful for facilitating discussion between FDA and sponsors, and at times, they prefer the virtual space to an in-

person meeting because it allows staff to join from any location and reduce travel time and resources. Industry reiterated that having cameras on during these meetings is important to them because it allows for non-verbal facial expressions similar to in-person interaction. FDA stated that having cameras on for those with a primary speaking role is the policy, however, there may be instances where individual circumstances have prevented that for various reasons.

FDA described that there are several best practices for sponsors to ensure an efficient and effective virtual meeting, including forgoing lengthy introductions (as previously described), alerting the FDA host to any technical issues immediately as they arise, having core participants arrive 5 to 10 minutes before the official start time to test audio and visual components, and having experienced technical staff on both sides monitoring participants and ensuring connectivity so that everyone may participate fully.

Post-meeting Addendum

Industry prepared the following additional talking points related to this topic, but due to time limitations these were not discussed during the meeting:

- There have been situations in which the escort process was challenging. For example, sponsors have noted instances in which escorts may have been late greeting sponsors and taking them to the meeting room. Industry would encourage FDA to be stricter about setting up these logistics, providing adequate staffing at security, and anticipating arrival of sponsor staff to ensure escorts are arriving with enough time to greet everyone and bring them to the meeting room so that the meeting can start on time.

Panel Discussion 6 – INTERACT and Type D Meetings

The sixth panel discussion of the workshop focused on experiences with and best practices for both INTERACT and Type D meetings.

On the subject of INTERACT meetings, FDA emphasized that Industry needs to ensure that the criteria for the request are met, namely that it is not so early that the product or indication is not identified, or late enough that the manufacturing process is defined or definitive toxicology studies have been started. The request should be descriptive so that FDA can understand the issues that sponsors want to address prior to the submission of an IND and how the information gained will impact future submission. The meeting request should also be multidisciplinary as necessary to answer the questions. If sponsors are planning for a product with multiple indications in CBER OTP, then they should consider requesting a platform technology meeting. Industry stated that they are still learning the procedures and context for INTERACT meetings, and they face uncertainty about the type and number of the questions and the timing of the meeting, which is reflected in the higher proportion of INTERACT request denials. They noted that additional training and guidance could be helpful to mitigate this, particularly because the meeting denials and conversions that have been occurring could be prevented with improved sponsor education. Industry added that since CBER has more experience with INTERACT meetings, they want to ensure that there is communication, collaboration, and consistency across CBER and CDER with the way that they handle INTERACT meeting requests.

For Type D meetings, FDA emphasized that Industry needs to ensure that the scope of the request is appropriate for a Type D meeting, both in terms of the number of disciplines required for review and the complexity of the review. The meeting should have a narrow focus of issues at key decision points that need critical feedback to move the program forward. It should be limited to no more than two focused topics and require no more than three review disciplines. If sponsors have more than two focused topics, a highly complex single issue that includes multiple questions and require more than three disciplines, then a Type C meeting should be requested. Industry stated that they have been having positive experiences with Type D meetings overall, and they appreciate that the faster timeline allows them to receive rapid answers to critical, focused questions. However, sponsors continue to receive meeting type conversions and would like to have further details on the rationale when it occurs.

Additionally, Industry noted that while one of the purposes of Type D meetings was originally to support general questions about innovative approaches that do not require extensive, detailed advice, Type D meetings seem to be used more frequently for answering simple, single-topic questions. FDA agreed that this has been their experience in their review divisions as well.

Post-meeting Addendum

Industry prepared the following additional talking points related to this topic, but due to time limitations these were not discussed during the meeting:

- It would also be helpful to build out processes around other mechanisms, like CBER's Advanced Technology Team (CATT), not only to be able to better utilize them generally, but also to understand the relationship between CATT and INTERACT meetings.
    - It's not particularly clear how the outputs from a CATT meeting can be leveraged into an INTERACT meeting, for example, and not having timelines associated with CATT contributes to that unpredictability, even though in theory, "complex manufacturing technologies or processes" are in-scope for INTERACT.
- Regarding conversion of a request to a different meeting type, Industry has had a few cases where they have requested a meeting with a longer timeframe, like Type C, and FDA has converted it to a Type B with a shorter timeframe, and that is appreciated, when warranted, as a best practice.

Public Comments

While registering to attend the workshop, attendees were given the opportunity to indicate that they would like to offer public comments to FDA during the workshop, an option which was available regardless of in-person or virtual attendance. To ensure that the public comments fit within the time constraints of the workshop, FDA invited comments on a first-come, first-served basis and required that commenters confirm their desire to comment and send their presentation materials by specific dates in order to be eligible to present. Following this process, three attendees confirmed that they would offer comments. The following comments represent the opinions of the speakers and are not indicative of FDA thought, guidance, or policy.

The first public commenter was Anne-Virginie Eggimann, M. Sc., the Chief Regulatory Officer of Tessera Therapeutics, Inc, a genome editing company. Ms. Eggimann provided a series of eight recommendations for meeting management with sponsors, listed in order of decreasing impact:

1. Shorten time from receipt of request to meeting and issue minutes in <30 days whenever feasible, especially for meetings where FDA responses are rate limiting for development.
2. Adhere to time allocated for Sponsors to review FDA preliminary responses prior to meetings.
3. Keep option to request either fully virtual, hybrid, or all in-person "face-to-face" meetings. Avoid granting teleconference or WRO when sponsors asked for a "face-to-face" interaction.
4. Establish cloud-based ESG NextGen with capability to track meeting process (e.g., "received," "reviewing," "responded") and allow efficient correspondence between Sponsors and RPM & Reviewers.
5. Allow opportunity to request CMC-focused meetings during development in addition to existing meeting types.
6. Create standardized template for meeting requests using electronic portal with "intake form" to streamline process and facilitate meeting date scheduling.
7. Actively support Communication Plans throughout development for Breakthrough Therapy and RMAT designated products; ideally with senior staff involvement for at least EOP meetings.
8. Set maximum number of pages for briefing packages (not including appendices). This should help Sponsors be more concise, clear, and direct.

The second public commenter was Marcia D. Howard, Ph.D., CAE, the Vice President of Regulatory and Scientific Affairs of the Consumer Healthcare Products Association (CHPA). Throughout her comments, Dr. Howard described that while their nonprescription and OTC drugs are regulated as NDAs and subject to the same timelines and fees as prescription drugs, they do not feel as though they have the same opportunities to provide feedback to the FDA on PDUFA processes outside of public forums and docket comments. She asked that FDA consider further mechanisms for CHPA and other OTC drug organizations to play an active role in providing input on improvements to the NDA meeting process.

The third public commenter was Gail Trauco, RN, BSN, the CEO and Managing Member of The PharmaKon LLC, a mobile nursing company serving the United States. While she noted that FDA and Industry have already covered the best meeting practices that she planned to discuss in her comments, she emphasized a core need for FDA to create an inclusive environment, particularly for the LGBTQ+ community, the needs of whom Trauco stated the current clinical trial processes may not be meeting. She called for FDA to encourage diverse perspectives and equal participation without bias, promote open dialogue, avoid imposing biases on attendees, and utilize multiple languages as needed.

Conclusion

FDA and ERG thanked the workshop panelists, presenters, and attendees for their feedback related to PDUFA formal meeting management. Throughout the workshop, as FDA and Industry shared their perspectives on the topics related to meeting management, there was a sense of collaboration, of FDA and Industry coming together to ensure that they can work as effectively as possible to bring safe, effective drugs to the public. Industry emphasized that it is helpful for them to receive clear and complete feedback at multiple points throughout the drug development process so that they may make informed decisions about their development program. FDA described their commitment to working with

Industry to achieve shared goals, develop common understanding, and provide meaningful advice. FDA noted that it is helpful for them to receive clearly articulated questions, complete background packages, and appropriate requests for the stage of development to meaningfully provide advice. Overall, there was a genuine interest and commitment among FDA and Industry to not only share their perspectives and communicate their own interests, but also to gain a better understanding of the other party.