Public Workshop on Meeting Management Best Practices
July 22, 2024
AI Generated Transcript

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00:00:07.170 --> 00:00:08.600
TELEPHONE_USER: Hello, okay.

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00:00:08.810 --> 00:00:13.559
TELEPHONE_USER: good morning, and welcome to the public workshop for meeting management best practices.

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00:00:13.900 --> 00:00:23.470
TELEPHONE_USER: My name is Danielle Villata. From the office of strategic programs at FDA's Center for Drug Evaluation and Research. I'll be the host of today's workshop.

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00:00:28.640 --> 00:00:40.369
TELEPHONE_USER: Timely and effective communications with sponsors during drug development is a core agency activity to help achieve the agency's mission to facilitate the conduct of efficient and effective drug development programs

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00:00:40.840 --> 00:00:47.130
TELEPHONE_USER: through the Prescription Drug User Fee Act. FDA has established numerous meeting opportunities with sponsors.

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00:00:47.860 --> 00:00:56.300
TELEPHONE_USER: The purpose of today's public workshop is to fulfill a PDUFA 7 commitment to hold a public workshop, to discuss best practices for meeting management

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00:00:57.090 --> 00:01:01.279
TELEPHONE_USER: and learning from today's discussion could inform FDA's internal processes

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TELEPHONE_USER: improvement efforts.

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00:01:06.440 --> 00:01:11.559
TELEPHONE_USER: We have a full agenda for today's meeting to start off. We'll provide introductions to today's speakers.

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00:01:11.710 --> 00:01:15.239

TELEPHONE_USER: Next, FDA will provide an overview of PDUFA meeting metrics.

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00:01:15.740 --> 00:01:24.240
TELEPHONE_USER: The rest of the day will be dedicated to panelist discussions between FDA and industry representatives providing their perspectives on the topics you see below.

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00:01:24.960 --> 00:01:32.040
TELEPHONE_USER: We'll have 2 breaks during the day, and we'll conclude the formal portion of our meeting at 1.3 0 and open it up for public comments. At 2

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00:01:35.390 --> 00:01:41.939
TELEPHONE_USER: we invite you to submit comments to the public docket, which will remain open until August 20, second 2024.

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00:01:42.250 --> 00:01:47.000
TELEPHONE_USER: As a reminder, a recording and transcript of this workshop will be posted to the web page.

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00:01:47.140 --> 00:02:02.349
TELEPHONE_USER: I invite any in-person attendees. If you have any questions about the workshop logistics to come, find me, and if any virtual attendees have any questions feel free to email me, and I will now hand it over to our moderator of today's meeting. Valerie Overton.

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00:02:07.600 --> 00:02:09.190
TELEPHONE_USER: Thank you, Danielle.

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00:02:09.669 --> 00:02:22.280
TELEPHONE_USER: and good morning, everyone. So thank you so much for joining us for this workshop on best practices for meeting management and the Prescription Fee User Fee Act.

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00:02:22.450 --> 00:02:31.640
TELEPHONE_USER: or PDUFA. My name is Valerie Overton. My pronouns are she her and I'm with ERG, which is a contractor to FDA,

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00:02:32.190 --> 00:02:40.749
TELEPHONE_USER: and I'll be moderating today's program. So thank you so much for joining us, whether in person or virtually.

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00:02:40.840 --> 00:02:45.440

TELEPHONE_USER: and, as you can see, I am joined here by

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00:02:45.930 --> 00:02:54.559
TELEPHONE_USER: the presenter for this morning, and a group of 9 panelists who will be discussing the various topics that you saw on the agenda.

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00:02:56.030 --> 00:03:00.700
TELEPHONE_USER: So I'd like to start out by doing some introductions.

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00:03:00.830 --> 00:03:02.909
TELEPHONE_USER: So for our panelists

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00:03:05.420 --> 00:03:17.499
TELEPHONE_USER: we have from the Center for Drug Evaluation and Research or CDER. We have Jennifer L. Mercier, the office director of the Office of Regulatory Operations in the Office Of New Drugs.

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00:03:18.740 --> 00:03:27.219
TELEPHONE_USER: Banu Karimi-Shah, the Deputy Division director of the Division of Pulmonology, Allergy, and Critical Care in the Office Of New Drugs.

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00:03:28.860 --> 00:03:31.620
TELEPHONE_USER: and Pamela Lucarelli.

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00:03:32.030 --> 00:03:41.079
TELEPHONE_USER: the division director of the division of Regulatory Operations for Rare Diseases, Pediatrics, Urology and Reproductive Medicine in the Office of New Drugs

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00:03:42.710 --> 00:03:49.409
TELEPHONE_USER: from the Center for Biologics, Evaluation and Research, or CBER. I am joined by Sonday Kelly.

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00:03:49.420 --> 00:03:57.890
TELEPHONE_USER: the division director of the Division of Regulatory Operations and Regulatory Programs in the Office of Regulatory Operations.

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00:03:58.390 --> 00:04:06.380
TELEPHONE_USER: and Ramani Sista, the office director of the Office of Review Management and Regulatory Review in the office of Therapeutic Products

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00:04:07.560 --> 00:04:16.259
TELEPHONE_USER: from industry. I'm joined by Alex May the North America Lead for the Regulatory Science, Policy, and Intelligence from CSL Behring

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00:04:16.940 --> 00:04:25.050
TELEPHONE_USER: Brad Jordan, the Associate Vice President for Regulatory Policy and Strategic and Strategy from Eli Lily and Company.

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00:04:26.866 --> 00:04:34.099
TELEPHONE_USER: Alison Maloney, the Head And Vice President For Regulatory Affairs, North America from Bayer

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00:04:34.750 --> 00:04:46.210
TELEPHONE_USER: and Liza O'Dowd from global regulatory affairs, immunology, global policy and regulatory intelligence and North American liaison, Janssen, Inc. From Johnson and Johnson.

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00:04:46.840 --> 00:04:48.740
TELEPHONE_USER: Welcome to our panelists.

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00:04:49.780 --> 00:04:59.330
TELEPHONE_USER: I'll now introduce Mr. Paul Phillips, the Director Of Office Of The Office Of Program Operations In CDER’s Office Of New Drugs.

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00:04:59.470 --> 00:05:08.269
TELEPHONE_USER: who will be presenting an overview of PDUFA meeting metrics to set the foundation for today's panel discussions.

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00:05:08.590 --> 00:05:10.369
TELEPHONE_USER: So welcome, Mister Phillips.

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00:05:22.030 --> 00:05:24.359
TELEPHONE_USER: They don't make these things for tall people

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00:05:24.370 --> 00:05:48.669
TELEPHONE_USER: all right. Thanks so much, Valerie. If I stand like this. Can you hear me? Okay, I'm talking this far from the microphone. Okay, great. So, thanks, Valerie. I appreciate the introduction just a little bit more about me and my background. So I was actually had the privilege to be involved with the PDUFA 7 negotiations, including the development of the commitment that led to this meeting today. So I am grateful for the opportunity to

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00:05:48.670 --> 00:06:12.989
TELEPHONE_USER: present some information, some metrics, and some data points, both which were included specifically in the commitment, and some of which were agreed upon between FDA and industry in advance of today's meeting. So we'll go ahead and get started. To begin with, what I'd like to do is actually go into some history of formal meetings between FDA and industry to talk a little bit more about how we got to where we are today

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00:06:12.990 --> 00:06:14.490
TELEPHONE_USER: formal meetings.

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00:06:14.490 --> 00:06:31.710
TELEPHONE_USER: So formal meetings between FDA and industry actually began a little less than 3 decades ago in 1997. During the second iteration of PDUFA. At that time there were 3 specific meeting types created formal meetings, type A type B and type C,

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00:06:32.050 --> 00:06:54.340
TELEPHONE_USER: with each of those 3 meetings there were 3 specific performance goals that were established with timelines to act upon those 3 different goals, the 1st of which was responding to the meeting request itself, meaning. The FDA would make a decision whether to grant or deny the meeting within a certain time frame for each of those 3 types.

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00:06:55.480 --> 00:07:01.020
TELEPHONE_USER: The second goal was related to scheduling and holding the meeting within a certain time frame.

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00:07:01.080 --> 00:07:18.099
TELEPHONE_USER: and then the 3rd of course, was for issuing meeting minutes. Once the meeting had been held. I think it's noteworthy that of those 3 initial simple goals, 2 of the goals and the timelines associated with those have remained unchanged for almost 3 decades since their inception.

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00:07:18.930 --> 00:07:21.580
TELEPHONE_USER: So what has changed since that time point

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00:07:21.730 --> 00:07:38.099
TELEPHONE_USER: in PDUFA 3. The 1st of those 3 goals was adjusted for your type B and type C meetings to allow FDA up to 21 days to respond and to make a decision whether or not to grant or deny the meeting, while the type A was held consistent at the original fourteen-day timeline.

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00:07:38.440 --> 00:08:07.620
TELEPHONE_USER: The next change occurred in PDUFA 5, where a new meeting format was instituted. Specifically the written response only, or what we often refer to as a WRO. What that refers to is instances where, based upon the nature of the questions. FDA, they may be more straightforward, and FDA is able to simply issue its guidance and advice in response to sponsors' questions as written advice in lieu of a formal meeting.

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00:08:09.410 --> 00:08:17.100
TELEPHONE_USER: that specifically applied at the time to the subset of type B meetings called Pre. IND. And also to type C meetings.

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00:08:17.740 --> 00:08:20.609
TELEPHONE_USER: The next change took place in PDUFA, 6,

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00:08:20.640 --> 00:08:29.740
TELEPHONE_USER: where there were a subset of type B meetings that were pulled out specifically the end of phase meetings and given their own set of timelines and metrics related to those.

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00:08:30.140 --> 00:08:42.289
TELEPHONE_USER: And then the last change, of course, took place in the most recent iteration of PDUFA negotiations, or PDUFA, 7, where there were 2 brand new meeting types established type D and interact, which I'll talk more about a little later.

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00:08:42.400 --> 00:09:03.779
TELEPHONE_USER: One item to note that's not on the slide. That was also a change in PDUFA 7 was FDA, and Industry established a brand new mechanism or a formal mechanism for industry to be able to request clarification of FDA's meeting minutes and written response only to ensure that FDA understood the information contained in those documents.

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00:09:05.890 --> 00:09:10.979
TELEPHONE_USER: So that brings us to where we are today, which is our current meeting types type A through interact.

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00:09:11.250 --> 00:09:21.300
TELEPHONE_USER: I'm going to briefly now, just walk through each of these with a high-level description. You can read more about these in our formal meeting's guidance, which is available on our public website. If you wish to do so

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00:09:21.900 --> 00:09:50.929
TELEPHONE_USER: so for type a meetings. Those are typically intended for a stalled development program. And what do I mean by that? So, for

example, there may be instances where a clinical development program goes on clinical hold meaning there's most often are typically a safety issue that prevents the program from moving forward. And that issue needs to be resolved and addressed before dosing in humans can continue and type. A meetings are the mechanism through which that interaction between FDA and industry can occur.

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00:09:52.270 --> 00:10:10.070
TELEPHONE_USER: Type B, there's 2 of which there are 2 categories. Now, as I mentioned earlier, is generally your milestone meetings. So I already talked about the end of phase meetings as a subset of those, and then the other type, B's are all other milestone meetings, including, for example, pre-ind meetings.

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00:10:10.740 --> 00:10:22.179
TELEPHONE_USER: Then we have our type C meetings, which is kind of the catch-all category. So if there's a meeting type that doesn't a meeting request that doesn't fall into one of any of the other types, then it generally falls into the type. C meeting

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00:10:22.960 --> 00:10:30.700
TELEPHONE_USER: type d, 1 of our newer meeting types is for narrow issues at key decision points in the development program other than milestones.

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00:10:30.720 --> 00:10:42.639
TELEPHONE_USER: And typically, this is a fewer number of questions that require a limited number of FDA disciplines to respond to in order for companies to get information, they need to make those key decisions and move forward.

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00:10:43.260 --> 00:10:57.250
TELEPHONE_USER: The last is the interact meeting which is to address novel and unprecedented questions early in the development program. So prior to the pre-ind stage, another way to think about this is this really is to discuss

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00:10:57.280 --> 00:11:19.850
TELEPHONE_USER: issues for which there is not readily available guidance when companies are thinking about and beginning to design your IND enabling studies. So, for example, your non-clinical studies, perhaps some of your chemistry, manufacturing and controls work. So it's before those begin where there are questions that would be necessary to answer in order for a company to move forward.

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00:11:20.340 --> 00:11:46.889
TELEPHONE_USER: One other point I want to make about the interact meetings is that some of you may know this, but some of you may not. The

center for biologics actually initiated these as a pilot before they were part of the formal meetings paradigm several years ago, and due to the success that CBER found with those. It was requested, during PDUFA. 7, that they become part of the formal meetings, paradigm, and be expanded to include products from both CDER and CBER, which they were

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00:11:49.350 --> 00:11:50.280
TELEPHONE_USER: all right.

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00:11:51.800 --> 00:12:19.270
TELEPHONE_USER: So this slide is, I think, an interesting one, and we share it just to kind of give you a sense of what the number of meetings FDA receives looks like. So if we look at the past decade of meetings that FDA's formal meetings, FDA has held. The 1st thing you probably readily notice, is beginning in fiscal year 2013. There's an incremental but steady increase year over year in the number of meetings that FDA received and granted and held.

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00:12:19.767 --> 00:12:27.280
TELEPHONE_USER: Probably not surprisingly. You see, a large jump in fiscal year 2020. With the onset of the COVID-19 pandemic.

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00:12:27.550 --> 00:12:42.239
TELEPHONE_USER: we did our best to roughly estimate the number of meetings that were specifically to address the Covid pandemic, so products to either prevent or treat covid, and tried to subset those out in the gold bars

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00:12:42.240 --> 00:13:04.499
TELEPHONE_USER: beginning in fiscal year 20. And what you notice as you move into subsequent years is a somewhat steady decline again, as the pandemic wound down, and then eventually, in 2023, when the Public Health emergency was allowed to expire again. Not surprisingly, the number of Covid product related meetings also decreased over that time.

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00:13:05.223 --> 00:13:22.379
TELEPHONE_USER: While we don't have the fiscal year 2024 data yet. We're still in the middle of that. So we don't know what that will look like. What I anticipate will see either next year or the year after. Is that as those Covid meetings begin to level out to

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00:13:22.380 --> 00:13:39.889
TELEPHONE_USER: the percent that would be commensurate with other product types. And we see the non-covid meetings pick back up. We will probably likely see a steady increase again year over year, and meetings, and that downward trend will reverse again. At least, that's my prediction, and we'll see if that we'll see if that pans out in the coming years.

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00:13:40.535 --> 00:13:50.074
TELEPHONE_USER: One other point I'll just make with this to kind of put this in context for anyone that is kind of trying to understand. What does it mean to have 4,000 meetings a year?

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00:13:51.170 --> 00:14:17.330
TELEPHONE_USER: if you take that number divided by the number of business days that FDA employees are working and available to meet, that averages out to about 17 meetings a day on every single business day of the year, meaning some days there may be more, and some days they may be less. But I just state that to point out that, as you can see, a significant proportion of our resources and time do go into meeting with industry to discuss their specific product development questions.

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00:14:19.550 --> 00:14:26.570
TELEPHONE_USER: Now we'll turn our attention to talk a little bit more about meeting types and meeting formats and discuss some data related to these.

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00:14:26.780 --> 00:14:49.320
TELEPHONE_USER: Before I do that, I want to just provide some context and point out that the ultimate meeting type and meeting format that is granted is the decision of FDA. And it's based upon the nature of the questions that are included in the meeting request. It's based upon the stage of the product development program and the intent of the meeting along with several other items. The review teams consider those

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00:14:49.320 --> 00:14:59.020
TELEPHONE_USER: and decide what the most appropriate meeting type will be based on the intent of those types, as I outlined a few minutes ago, and then ultimately, that is what is granted.

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00:14:59.100 --> 00:15:04.989
TELEPHONE_USER: The natural question might come, how often does FDA grant the same type of meeting that is requested?

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00:15:06.090 --> 00:15:13.190
TELEPHONE_USER: So what you see on this slide is on the left hand side in the 1st column, each of the meeting types that we have today.

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00:15:13.480 --> 00:15:20.429
TELEPHONE_USER: I'll just note the very last row says, no meeting type. What that means is that in some rare instances we do receive requests

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00:15:20.460 --> 00:15:30.180
TELEPHONE_USER: from sponsors where they do not specify a meeting type. They simply provide some questions and a request for a meeting. And so that's what that represents.

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00:15:31.360 --> 00:15:35.500
TELEPHONE_USER: As you move to the right in the table. The second column says, sample.

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00:15:35.660 --> 00:15:39.829
TELEPHONE_USER: what that means is that for type A through type? C,

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00:15:39.880 --> 00:15:48.170
TELEPHONE_USER: we looked at data for 3 fiscal years. Fiscal year 2021, 22, and 23 to capture data.

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00:15:48.170 --> 00:16:11.109
TELEPHONE_USER: Now this was a little bit difficult, because the meeting type that's requested is not part of our standard data elements in our system. So we had to do this manually. So that sample is the sample size. It's not representative of the complete number of meetings received of these types during those fiscal years, but it is a representative sample proportional to the same proportion of meetings that were requested of each type during that year.

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00:16:11.400 --> 00:16:27.890
TELEPHONE_USER: The exception is the type D and interact meetings which, as you know, were instituted in fiscal year 23, with PDUFA 7. So we only have one complete year's worth of data for those meeting types. And so we were able to capture the full cohort of meetings for those 2 types.

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00:16:28.200 --> 00:16:48.579
TELEPHONE_USER: With that, I'll just mention that if you look at our Fy 2023 Congressional report on performance, these numbers will not match it. They're more updated. So you get the news here. They will be reflected in our Fy. 24 report, and the practical reason for that is that you can imagine if we receive a meeting request on September 30, th which is our cutoff point for the data

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00:16:48.913 --> 00:16:55.579
TELEPHONE_USER: it may take several weeks before that meeting type is adjudicated, and it may need to later be updated and changed. So

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00:16:56.035 --> 00:17:02.089
TELEPHONE_USER: with that being the data that we looked at. The next thing I'll draw your attention to is the dark blue squares.

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00:17:02.160 --> 00:17:30.220
TELEPHONE_USER: If you start in the top left of the table with the 1st dark blue square at 81%. What that represents is that 81% of the meetings that were requested as a type A were also granted by FDA as a type A, and as you move diagonally down from the top, left to the bottom right. You can pretty quickly see that more than 80% of the time, and in some instances more than 90% of the time. FDA grants the same type of meeting that industry requests.

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00:17:30.440 --> 00:17:34.409
TELEPHONE_USER: Remaining percent are spread across the other meeting types. As you can see here.

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00:17:37.950 --> 00:17:40.989
TELEPHONE_USER: All right. So let's talk a little bit about the meeting format now.

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00:17:41.720 --> 00:17:55.720
TELEPHONE_USER: So what do I mean by meaning format? This is the format in which FDA communicates our regulatory advice and guidance to industry about their specific product development program and the questions that have been raised about that program.

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00:17:56.150 --> 00:18:04.450
TELEPHONE_USER: There are 3 primary formats in which FDA currently does that. And I'm going to walk through those. Briefly. The 1st is the face-to-face format.

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00:18:04.610 --> 00:18:26.790
TELEPHONE_USER: I will note here as a side note that during PDUFA 7 the definition of a face-to-face meeting was expanded to capture lessons learned from Covid-nineteen. Specifically what we found is we were all forced to do things virtually as we couldn't meet in person anymore, we found that we could very effectively hold face-to-face meetings, virtually meaning

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00:18:26.890 --> 00:18:36.800
TELEPHONE_USER: through some online medium that included both audio and video component for that richer interaction where you can see facial expressions and see people as you're speaking to them.

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00:18:37.110 --> 00:18:47.020
TELEPHONE_USER: So a face-to-face meeting now can be held in either an in person format or in a virtual format, and that's captured in the user fee agreement letter. Formally.

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00:18:47.350 --> 00:19:05.569
TELEPHONE_USER: the second primary format is a teleconference which does still exist, at least, for right now it's used much less frequently, as you might imagine. Now that we have those virtual options with the video, but it does still exist, and there are still occasions when it is used or requested by sponsors. And that just simply means it's an audio. Only conversation.

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00:19:06.260 --> 00:19:12.959
TELEPHONE_USER: The 3rd and final format is the written response only which I mentioned previously came into being as part of PDUFA 5.

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00:19:13.120 --> 00:19:16.510
TELEPHONE_USER: And I and I described what, what and how that is used.

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00:19:18.220 --> 00:19:22.819
TELEPHONE_USER: taking a step back, I'd like to just point 2 things out. One is that

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00:19:22.880 --> 00:19:35.079
TELEPHONE_USER: from an industry standpoint industry can request any of these meeting types, or excuse me, any of these meeting formats for any of the meeting types, and that would be considered by FDA.

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00:19:35.540 --> 00:19:59.590
TELEPHONE_USER: Conversely, what you see in the table at the bottom here is FDA should only unilaterally convert or grant a WRO for certain meeting types. Not all. And that may be somewhat obvious when you look at the difference, but type for type A and all non-pre-ind type. B's FDA should not unilaterally convert it to a WRO unless it was requested that way by the sponsor.

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00:19:59.590 --> 00:20:11.930
TELEPHONE_USER: But for those 2 meeting types, as you can imagine, due to the nature of the discussions. Those more often than not require that live interaction to really work through some of those issues and questions that are being discussed

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00:20:12.770 --> 00:20:26.130
TELEPHONE_USER: alternatively for the type B, pre. 90 subset, and then subsequently CD. And interact. FDA may grant A. WRO. Is one instance when there are instances that that's the most effective way to communicate that information.

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00:20:26.630 --> 00:20:34.929
TELEPHONE_USER: The natural question that might come to your minds and we certainly get often at FDA is so how frequently do you then make those conversions to WRO FDA?

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00:20:36.090 --> 00:20:38.860
TELEPHONE_USER: This slide answers that question.

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00:20:39.060 --> 00:20:51.279
TELEPHONE_USER: Maybe not surprisingly, type B pre-ind has the largest percent conversion at 57% of the pre-ind meetings that we receive that are requested in some other format or converted to a WRO

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00:20:51.903 --> 00:21:11.339
TELEPHONE_USER: pre, and Ds are among the most frequent meeting types that we have. Because, as you can imagine, if someone engages in a drug development program, that's the 1st interaction with FDA. And if you don't have an interact meeting it's so not only being the most common, it is probably also the meeting stage of development for which we have.

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00:21:12.560 --> 00:21:13.460
TELEPHONE_USER: Thank you.

110
00:21:15.816 --> 00:21:25.499
TELEPHONE_USER: It is also the stage. Oh, perfect! It's also I should have had that 10 min ago. All right. My mom told me I should have been born with a megaphone. And that helps.

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00:21:25.870 --> 00:21:48.870
TELEPHONE_USER: It's also the stage of development for which FDA actually has arguably the most advice publicly available. So you can imagine how a written response only for the most common questions that are frequently asked during pre-inds makes sense. Conversely, for interact, as I defined it earlier, which is for complex and novel questions for which there's typically no precedent

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00:21:48.870 --> 00:22:04.469
TELEPHONE_USER: for those ID enabling studies have the least percent conversion rate at 32%, for the reason that clearly those most often would benefit more from some sort of live interaction and meeting and type C and type D are between those 2 percentages.

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00:22:04.550 --> 00:22:12.240
TELEPHONE_USER: The last thing I'll note, as you can see in the footnote is that this data was pulled from fiscal year 2023. Again, when type D and interact were instituted.

114
00:22:14.630 --> 00:22:30.249
TELEPHONE_USER: So if we turn our attention now to today's paradigm for meeting goals that exist for the formal meetings between FDA and industry. This is it. Now, I'm not going to go through each of these in detail. There's a lot of information here, but I am going to kind of give you an oceanfront view if you will.

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00:22:30.530 --> 00:22:49.700
TELEPHONE_USER: walking through at a high level. What we have. So the 1st column on the left is today's meeting types A through interact. And as you move to the right, the next column represents the individual timeframes by meeting type within which FDA has to respond with its decision of whether or not to grant or deny the meeting.

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00:22:50.300 --> 00:23:05.600
TELEPHONE_USER: If we move, then again to the next column to the right, or the 3rd column over. This is actually the timeline for industry by which they need to submit their meeting packages to the FDA. There's no performance goes related to that.

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00:23:06.040 --> 00:23:29.349
TELEPHONE_USER: The next column over to the right or 4, th is FDA's timeline for providing what we call preliminary responses to the sponsor's questions to them in advance of the meeting. For those who may not be familiar with this. What that is is, the agency goes through the sponsor's questions, and all of the material provided develops our best and current advice at the time in response to those questions, writes it down.

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00:23:29.550 --> 00:23:52.510
TELEPHONE_USER: and then we share that with a sponsor in advance of that formal meeting. Sponsors then typically take that, and they take a couple of days to digest that and decide which of those responses they feel would be most beneficial for discussing, live at the meeting where they want to ask further clarifying questions, or better understand FDA's position on that, and then that begins to form the basis for those discussions at the meetings.

119
00:23:52.950 --> 00:24:19.190
TELEPHONE_USER: I'll pause there to note that there are occasions, and not rarely, but somewhat periodically, where sponsors will receive that preliminary advice, and it's straightforward enough, and they feel that they understand it, that they determine there is no need to hold the meeting. And so the next column over represents the timeline within which the sponsor should notify the FDA that we can cancel the meeting, and that the preliminary responses were clear and sufficient.

120
00:24:19.190 --> 00:24:24.300
TELEPHONE_USER: When that happens, those preliminary responses then become the official advice from the FDA.

121
00:24:24.740 --> 00:24:40.490
TELEPHONE_USER: The second to last column, then, is the goal for scheduling and holding those meetings or issuing the written response if it is a written response, and then, lastly, the final column represents the timeframe that FDA has within which to issue our meeting minutes when a meeting is held

122
00:24:42.690 --> 00:25:05.149
TELEPHONE_USER: all right, so you might immediately go into a blank stare. When you see this wall of data. There is a reason for this. We actually grappled with many different ways of presenting this. The 1st thing I'll say is that none of this is new. This is all accessible and available in our publicly available annual reports to Congress with our performance. But this does represent our performance on the

123
00:25:05.180 --> 00:25:10.760
TELEPHONE_USER: data or on the goals that I just walked through on the previous slide for the past 6 years.

124
00:25:11.020 --> 00:25:35.059
TELEPHONE_USER: We chose to do it this way for a couple of reasons. One is because there are some nuances in here that we couldn't really demonstrate graphically, very well, and secondly, because it is a much richer data set, and there are those of you who, I suspect, may want to spend some time with these slides when we make them publicly available after today's meeting, and this will allow you to do so again, it's available in our public reports. But this pulls 6 years worth of data

125
00:25:35.060 --> 00:25:49.209
TELEPHONE_USER: in a single slide for you. The last thing that I want to orient you to on this before I start to talk about the data itself is to call out that you'll notice that type D, and interact meetings are not included on here. And there's 2 reasons for that

126
00:25:49.210 --> 00:26:17.609
TELEPHONE_USER: one. We don't have 6 years worth of data to show any trends for those. Obviously, the second is because while our standard for performance on any of these goals is typically 90% type D and interact are new enough that just as with other newer commitments, there is typically a phase-in period meaning, we begin at a much lower standard of performance and then incrementally increase until we get to the point where we are at the 90% goal by the end of PDUFA 7.

127
00:26:17.870 --> 00:26:26.169
TELEPHONE_USER: So for those of you that are interested to see our performance in fiscal year 23 for type D and interact. Again, that is on our public website in our annual report to Congress.

128
00:26:27.160 --> 00:26:54.510
TELEPHONE_USER: But looking at what we have, the next thing you will probably notice is that it looks a little bit like Christmas with red and green on there. Okay, so what does that mean? So the red represents the data points at which FDA missed that performance goal in any given year. And the green represents where we made the goal. So I'm going to talk through this a little bit more now and provide some observations, and then I'll move on and allow you to draw your own conclusions as you look at this later.

129
00:26:54.510 --> 00:27:11.369
TELEPHONE_USER: So if you look at the 1st 4 rows in this table, those rows represent the meeting response goal I mentioned. That's the timeframe within which we have to make a determination whether to grant or deny the meeting. And this is for the different meeting types that we have.

130
00:27:11.370 --> 00:27:18.349
TELEPHONE_USER: Clearly, you can see that for type A and type. B. FDA met that response goal every year for the past 6 years

131
00:27:18.350 --> 00:27:42.370
TELEPHONE_USER: for Type B. In the phase. We missed it every year, but if you look closely you'll notice that there was a steady, increasing trend, and to the point where we only missed it by 2 or 3 percentage points in the last 2 years, and we would anticipate that with that continuing trend in the next year we would begin or 2. We would begin meeting that the last or the 4th row, rather the type C meeting response request. You can see there was 2 years where we missed it by one

132
00:27:42.370 --> 00:27:45.309
TELEPHONE_USER: percentage point, and we made it the other 4.

133
00:27:45.640 --> 00:27:56.659
TELEPHONE_USER: So overall, I think it's fair to say that FDA does quite well in meeting our goal for responding to requests with a decision within the timeframe for the majority of meetings.

134
00:27:57.640 --> 00:28:20.650
TELEPHONE_USER: Having said that when we move to the next section for scheduling the meetings or issuing written response only for those of you

here from industry, you're probably not surprised by this. This is where we struggle the most, and we have for many years. As you can see, it is a challenge, logistically and otherwise, we have found that that has been a struggle for us. So I'm going to point out a few things and then make a note here

135
00:28:20.710 --> 00:28:45.039
TELEPHONE_USER: about what we have been trying to do with that over the past 6 or 8 months. So when you look, you'll notice actually that there are some trends here, I would say in the positive or right direction. So Type B meeting scheduled and type C meeting schedules, there's a really clear trend of improvement when you look at Fy. 2018, through Fy 23 to the point where we're getting fairly close

136
00:28:45.070 --> 00:29:00.649
TELEPHONE_USER: to meeting the performance standard of 90%. For those. Also, when you look at the type A and type B in the phase written response. Only you can see again a trend for a consistent improvement. Looking from the year 2018, through 2023

137
00:29:00.890 --> 00:29:06.790
TELEPHONE_USER: to the point where the type B into phase written response. We actually met that goal in Fy 2023

138
00:29:07.130 --> 00:29:31.129
TELEPHONE_USER: for the others. It's fairly sporadic, I would say, some up and down, and not a real clear trend. But again, clearly they were missed. So this is not. We are not unaware of this. This is constantly on the mind of our senior leadership, and over the past 6 or 8 months we've been doing some work to take a look at our internal practices and evaluate our metrics, and try to better understand

139
00:29:31.320 --> 00:29:45.700
TELEPHONE_USER: where the problems lie and what are some of the things that we can do to try to impact this in the positive direction and make strides in the right direction. And perhaps we may even hear some things today during the panel discussion that will help us. So we look forward to that.

140
00:29:47.220 --> 00:30:11.640
TELEPHONE_USER: The last 2 things to point out on here are the second to last row, which is the preliminary response goal. And you can see again a steady, increasing trend to the point where in the last 2 years we've met that goal and finally meeting minutes similar to meeting response. I think it's fair to say that FDA, consistently for the last 6 years, has easily made that goal and done well in providing meeting minutes on time.

141

00:30:15.770 --> 00:30:22.450
TELEPHONE_USER: All right. Now we're going to turn our attention to talking about one of the metrics that was discussed in the commitment, which is

142
00:30:23.150 --> 00:30:26.039
TELEPHONE_USER: the number of in-person meeting requests

143
00:30:26.060 --> 00:30:39.249
TELEPHONE_USER: versus the number of held in meetings. In order to do that, we need to provide some context which will not be new to you. But I think it's helpful to start with. So PDUFA 7 begin in October of 2,022.

144
00:30:39.510 --> 00:30:58.250
TELEPHONE_USER: Everyone is, is very aware that that was still at a time when the COVID-19 pandemic was well underway and continuing to spread, and we were not meeting in person. No one was at that point in time, so the beginning of PDUFA 7 didn't allow us the opportunity to begin meeting in person and gathering metrics. Having said that

145
00:30:58.250 --> 00:31:11.949
TELEPHONE_USER: as the covid-nineteen pandemic wound down, and eventually then was allowed to expire, as I mentioned earlier in May of 2023 in advance of that expiration, Phe. Expiration, FDA already

146
00:31:11.950 --> 00:31:23.509
TELEPHONE_USER: planned and started to move toward holding in person meetings again. So in February of that year, before the May Phe expiration. We opened up and began holding type a meetings in person.

147
00:31:23.920 --> 00:31:28.930
TELEPHONE_USER: Then in June of that year we expanded to include Type B into phase meetings.

148
00:31:29.350 --> 00:31:47.930
TELEPHONE_USER: I'll stop there to point out that these are probably 2 of the more common meeting types pre-covid that FDA also held in person. So as we begin to move back to the pre-covid paradigm, if you will, of the types of meetings that FDA, historically and traditionally, has held much more frequently in person versus in some other format.

149
00:31:48.390 --> 00:31:59.359
TELEPHONE_USER: Finally, in January of this year, all meeting types were opened up for eligibility, to be held in-person with FDA depending upon the nature of the meeting and the questions.

150
00:31:59.360 --> 00:32:19.879
TELEPHONE_USER: So one other thing to note, you'll see in the footnote there in blue. I think it's interesting that while there were over a thousand meetings during this roughly one year and a month timeframe that were eligible from FDA's perspective to be held in person. Only about 18% of those were requested by industry to be held in person. So let's take a look at what we did with those when they were requested

151
00:32:21.180 --> 00:32:40.389
TELEPHONE_USER: similar to the performance. This could have been done in a graphical way, but only partially. You would have been able to digest part of the information much more readily, but it would have been lacking some of the nuances. And so again, we elected for this tabular format, for a richer data set for you to look at afterwards, but I'm going to sort of decode this for you now quickly.

152
00:32:41.140 --> 00:32:55.040
TELEPHONE_USER: So if you look at the 1st column on the left, you'll notice again the 3 phases that I just outlined of returning to in-person meetings with those timeframes associated with them, and each of the meeting types that were eligible and being held in person during that time. Frame.

153
00:32:55.640 --> 00:33:04.209
TELEPHONE_USER: The second column to the right represents the number of meetings of that type that were requested in any format during that time period.

154
00:33:04.860 --> 00:33:11.139
TELEPHONE_USER: The 3rd column represents the subset of those requests that were asked to be in person.

155
00:33:11.370 --> 00:33:22.939
TELEPHONE_USER: and the 4th column, which is in dark blue represents the number that were actually granted and held in person. So I'm going to point out. And then the types that were held in some other format subsequently.

156
00:33:23.581 --> 00:33:29.189
TELEPHONE_USER: I'm gonna use the type a in phase, one as an example, and just walk through this. So

157
00:33:29.690 --> 00:33:36.040
TELEPHONE_USER: between February and June of 2023 there were 49 meetings requested as type. A. 15 of those

158
00:33:36.090 --> 00:33:53.279
TELEPHONE_USER: were requested in person, and 13 were granted in person. 2 were virtual face to face. That was the initial phase of us coming back to in person. We were working through some internal communications. We noted that, and I'll just point out that that our intention was to hold all

159
00:33:53.360 --> 00:34:17.269
TELEPHONE_USER: meetings of type A that were requested in person as in person, so that was corrected in phase 2 and phase 3. And you'll notice that in phase 2, 28 were requested in person. 27 were held in person. Why, the one missing, if you go to the far right in the red column. You'll notice that that meeting was actually not able to be granted at all, for whatever the reasons. Maybe the meeting package was missing sufficient information to hold us up.

160
00:34:17.270 --> 00:34:27.630
TELEPHONE_USER: but the overall meeting was actually not able to be held, so, in other words, all meetings that were granted and held and requested as in person, were held as in person by FDA for type A.

161
00:34:28.900 --> 00:34:53.120
TELEPHONE_USER: As I alluded to a little bit ago, when you move down to the other meeting types, and I won't go through these individually, I'll allow you to do that later on your own. But you'll notice that the proportion of meetings that are requested versus held in person starts to change no longer. Is it 100% or the goal to be 100%. And part of that is because again, just as with the pre-covid paradigm, not all meetings as you get down in some of these, for example, type C meetings.

162
00:34:53.210 --> 00:35:07.809
TELEPHONE_USER: Really, is it necessary to hold that in-person robust discussion. And so, just as before, Covid, the nature and type of the meeting really will drive the format sensibly for what the most effective and efficient way is to communicate that information.

163
00:35:10.190 --> 00:35:19.099
TELEPHONE_USER: I'm going to go a little bit more in more granularly now into the 2 new meeting types type D and interact. And I'll begin with the type d.

164
00:35:19.470 --> 00:35:40.710
TELEPHONE_USER: so this represents data from the full fiscal year 2023 plus half of the current fiscal year 2024, quarter one and quarter 2. So it's the most up-to-date information we have basically, as the end of March 31st of this year, during that timeframe of about a year and a half, there was 858 meetings that were requested as type D.

165
00:35:40.890 --> 00:36:05.960
TELEPHONE_USER: Of those the large majority, 663 were granted as a type DA smaller proportion, 142 were more appropriate for some of one of the other meeting types, and thus were converted. And you can actually see in the second footnote down there that those conversions were spread across type C, type B, and in one instance it was actually converted to an interact meeting. And then there were a small number 53,

166
00:36:05.960 --> 00:36:14.299
TELEPHONE_USER: where the meeting was actually denied. And again, for whatever reason that was unable to, FDA was unable to move forward and hold Grant and hold the meeting

167
00:36:16.240 --> 00:36:19.389
TELEPHONE_USER: for that same time period for interact.

168
00:36:19.630 --> 00:36:35.479
TELEPHONE_USER: much fewer meetings, 212, just a little more than half of those were granted as interact. Only 13 of those were converted to another meeting type again spread across type B and type C, and in one instance it was converted to a type d.

169
00:36:36.230 --> 00:36:49.370
TELEPHONE_USER: But the most obvious data point on this slide is the large, much larger number of interact meetings that were denied with 86. I think the natural question that might come to your mind then is why so many more meetings with interact were denied.

170
00:36:50.230 --> 00:37:00.340
TELEPHONE_USER: So we went and took a look at all of the denial letters for the interact meetings and gathered the top 5 reasons for why those meetings were tonight. I'm gonna just

171
00:37:00.420 --> 00:37:23.599
TELEPHONE_USER: go through these at a high level with what you see on the slide here, but I'll just kind of put a PIN in this to say that there may be an opportunity later, during the panel discussion, depending upon timing to maybe go into a little bit more detail or granularity here, depending on some of the questions that come up with our panelists. But for now I'm just going to walk through these 5 top reasons. So one reason is that the questions were really more appropriate.

172
00:37:23.987 --> 00:37:32.250
TELEPHONE_USER: For a pre id meeting, not for not for interact. And what do I mean by that? So, as I mentioned, earlier, interact is really for

173
00:37:32.360 --> 00:37:33.620
TELEPHONE_USER: discussing

174
00:37:34.560 --> 00:37:54.729
TELEPHONE_USER: novel issues and questions that come up when a sponsor is thinking about designing your IND enabling studies. So you can imagine if you've already started those studies, and then you come to us with those questions, or even perhaps completed those studies. It's kind of a moot point. INTERACT's not going to help you. The next natural meeting to have is a pre-ind meeting.

175
00:37:55.450 --> 00:38:17.339
TELEPHONE_USER: The second reason we saw frequently was that the meeting package was missing information, or it was incomplete, and it didn't have adequate data, and without that it really is not. It's not a good use of either industries or FDA's time to then hold that meeting, because there's not sufficient information to have a complete and robust discussion, or provide complete answers to those questions.

176
00:38:18.170 --> 00:38:33.809
TELEPHONE_USER: And I'll just stop there to note that this. These are the reasons that are actually contained in the in the denial letters to sponsors. So sponsors would have seen these reasons and known these individually for their product development program, they would have known the reason why the meeting was denied.

177
00:38:34.800 --> 00:38:37.800
TELEPHONE_USER: A 3rd reason that we saw was

178
00:38:38.560 --> 00:39:04.969
TELEPHONE_USER: tied to a practice that actually CBER did during part of their pilot, as I understand it, which is that in some cases, when the request for the interact meeting would come in, I believe the information in that request was so clear and straightforward that center for biologics was able to directly provide regulatory advice to the sponsor at that time without a need to grant and hold a product-related meeting. And so the meeting was technically denied.

179
00:39:04.970 --> 00:39:12.520
TELEPHONE_USER: But the sponsor received advice nevertheless, and I believe that that practice continues today in the current formal paradigm.

180
00:39:13.810 --> 00:39:20.929

TELEPHONE_USER: The 4th reason that we saw was one that's really not just applicable to interact, but should be

181
00:39:21.180 --> 00:39:50.609
TELEPHONE_USER: noted for any meeting, and that is that sponsors sometimes tried to bundle multiple products and indications together. I imagine that those of you listening may be able to quickly recognize why that doesn't make sense. Each unique product and indication has its own pathway that it needs to go through for development, and the advice may not be the same for both. And so really to have a focused and effective meeting, you need to have a single product and indication identified. And that needs to be the focus of the discussion and the questions asked.

182
00:39:51.420 --> 00:40:06.599
TELEPHONE_USER: The final reason that we saw was that there was in some cases a need for further clinical development, or for not further clinical, but for further development on the intended clinical product. So let me give you an example of something I heard that fits this to say what we mean by that.

183
00:40:07.640 --> 00:40:31.999
TELEPHONE_USER: While this is much earlier in the overall drug development stage, there is also a guardrail on the front end, meaning you don't want to be too far along to have your interact meaning, but you have to have at least some thought have gone into it. So, for example, there were instances where we receive meeting requests where they had not even identified a product in an indication that's not very useful, because then there's no context for the discussion. So at a minimum

184
00:40:32.000 --> 00:40:41.250
TELEPHONE_USER: has to be a product and a single product and indication identified. And some thought having gone into what those id enabling studies would be with specific questions around that.

185
00:40:42.820 --> 00:40:54.930
TELEPHONE_USER: So with that, I think that concludes the data that we have to present to you that as mentioned by Valerie earlier, should hopefully provide a backdrop for our just panel discussion later today. And I'm going to go ahead and turn the time back over to Valerie.

186
00:40:59.900 --> 00:41:04.129
TELEPHONE_USER: Great! Thank you, Paul, for that very informative presentation.

187
00:41:05.480 --> 00:41:20.009

TELEPHONE_USER: So we're now going to transition to the panel discussion section of today's workshop. And so for each panel discussion I'll 1st name the discussion topic

188
00:41:20.020 --> 00:41:24.930
TELEPHONE_USER: and read the questions that we've asked the panelists to respond to.

189
00:41:25.770 --> 00:41:34.509
TELEPHONE_USER: I'll invite FDA panelists and industry panelists to answer the questions, giving each group up to 5 min.

190
00:41:34.900 --> 00:41:56.800
TELEPHONE_USER: Then we'll have open discussion among all the panelists for the remaining time in the panel discussion. So we've allocated 25 min for each discussion topic. So in general, that means about 5 min from FDA, 5 min from industry, and then about 15 min of discussion

191
00:41:57.240 --> 00:41:58.260
TELEPHONE_USER: more or less.

192
00:41:59.860 --> 00:42:00.810
TELEPHONE_USER: So

193
00:42:02.830 --> 00:42:10.210
TELEPHONE_USER: our 1st panel discussion topic is the general purpose and objectives of FDA industry meetings.

194
00:42:10.930 --> 00:42:13.909
TELEPHONE_USER: So we have 2 questions for the panelists.

195
00:42:14.850 --> 00:42:15.400
TELEPHONE_USER: First,

196
00:42:15.660 --> 00:42:21.479
TELEPHONE_USER: what are FDA's objectives that they hope to achieve when meeting with industry?

197
00:42:21.660 --> 00:42:23.740
TELEPHONE_USER: What are industry's objectives?

198
00:42:24.890 --> 00:42:33.290

TELEPHONE_USER: And second, are there best practices that would better achieve the objectives for meetings between FDA and industry.

199
00:42:34.420 --> 00:42:40.660
TELEPHONE_USER: So I'll start with 5 min for FDA, and I'll let you know, when you have 30 seconds remaining.

200
00:42:41.010 --> 00:42:46.060
TELEPHONE_USER: So someday, I believe you're going to lead off for FDA if you'd like to begin.

201
00:42:46.070 --> 00:43:01.659
TELEPHONE_USER: I am. Thank you, Valerie. Good morning, everyone very excited to be here. It's been many months preparation to get to this day, but we are here. Our computers are working. That's great, Valerie, did you want me to answer both questions? Yes, please. Okay.

202
00:43:01.660 --> 00:43:21.089
TELEPHONE_USER: right? Thank you. So FDA's main objective when we're meeting with industry is to facilitate regulatory compliance, give scientific advice. We really want to aid in the development in the review of I-n-d's for biologics and drugs, and also for future marketing applications.

203
00:43:21.090 --> 00:43:32.100
TELEPHONE_USER: We aim to facilitate your compliance with our regs and gain agreement on these future submissions. And if the submission is under review, possibly resolving some of our differences.

204
00:43:32.100 --> 00:43:55.019
TELEPHONE_USER: We typically talk about things like product development, clinical child design, facility, design. There are many topics that we can discuss with you. We believe that it's really important and critical that meetings are efficient and timely to provide advice and direction to help you through the development process. You'll hear us talk a lot about focus.

205
00:43:55.310 --> 00:44:14.640
TELEPHONE_USER: We really want the questions to be focused and appropriate for the stage of development that you are in. You heard Paul say earlier. It's not effective to come in for an interact and have multiple indications for your product. So you'll hear us throughout the day talking about focus questions related to the stage of development.

206
00:44:14.640 --> 00:44:37.539

TELEPHONE_USER: We really need background information relevant to that stage, but not overly voluminous, that we can't review it in these tight meeting timelines. And also we really want to avoid pre-review and all encompassing questions, such as does FDA have any comments on this protocol as you can imagine? That's difficult for us to answer, because there are

207
00:44:37.540 --> 00:45:01.739
TELEPHONE_USER: many factors that go into a clinical trial beyond the protocol. And so it's hard for us to point out everything that's wrong, not wrong, but everything we would have comments on that protocol also questions like, is our Cmc. Or Pharm talks acceptable? Those are difficult questions for us to answer, because imagine if we said yes, and then you proceeded, and there were other things that we didn't

208
00:45:01.740 --> 00:45:07.289
TELEPHONE_USER: discussed or didn't have prior knowledge during the meeting. So with the meeting package.

209
00:45:07.990 --> 00:45:09.216
TELEPHONE_USER: Thank you.

210
00:45:11.030 --> 00:45:17.669
TELEPHONE_USER: Thank you. Sunday. Other FDA folks would you like to add anything in the timer meeting?

211
00:45:19.590 --> 00:45:20.910
TELEPHONE_USER: Fine if you don't

212
00:45:20.950 --> 00:45:22.860
TELEPHONE_USER: just giving you the opportunity.

213
00:45:23.340 --> 00:45:24.430
TELEPHONE_USER: Okay.

214
00:45:24.690 --> 00:45:26.489
TELEPHONE_USER: all right. Thank you.

215
00:45:27.024 --> 00:45:35.060
TELEPHONE_USER: So now industry folks, I'm not sure which one of you will lead off. But great if you'd like to go ahead.

216
00:45:35.940 --> 00:45:52.189

TELEPHONE_USER: So good morning. As you heard. My name is Alison Maloney. I'm the head of regulatory affairs for Bayer pharmaceuticals. And I'm really pleased to be here. I actually almost didn't make it because of Amtrak scheduling. I don't know if anyone else had those problems today or yesterday.

217
00:45:52.470 --> 00:45:55.239
TELEPHONE_USER: So 1st of all, my comments are my own.

218
00:45:55.260 --> 00:46:05.339
TELEPHONE_USER: but they are derived from bear. The company I work for is experience as well as our interactions with Pharma and bioindustry associations.

219
00:46:05.610 --> 00:46:11.390
TELEPHONE_USER: I probably will take the 5 min. So here we go. I do have some prepared comments.

220
00:46:11.690 --> 00:46:24.869
TELEPHONE_USER: So industry or sponsors, I will use those terms randomly. General objective is to meet with FDA is to have a timely meeting.

221
00:46:24.890 --> 00:46:29.860
TELEPHONE_USER: have substantive and interactive, scientific and regulatory feedback.

222
00:46:30.000 --> 00:46:38.080
TELEPHONE_USER: and this really reduces our regulatory uncertainty and ultimately ensures safe and effective products are available to US patients.

223
00:46:39.600 --> 00:46:50.649
TELEPHONE_USER: These meetings serve to provide a forum for sponsors to get guidance from FDA, and sponsors, may provide proposals for FDA's review and seek agreement on necessary paths forward.

224
00:46:50.780 --> 00:46:58.669
TELEPHONE_USER: Sponsors see these meetings as an opportunity for collaboration with FDA rather than seeking simple yes or no answers.

225
00:46:59.030 --> 00:47:12.449
TELEPHONE_USER: I'd like to begin by having that in general. FDA is well prepared for meetings, and from my experience provides sponsors with valuable feedback to meet our objectives of reducing regulatory uncertainty.

226
00:47:12.530 --> 00:47:17.259
TELEPHONE_USER: FDA meetings and written feedback are extremely valuable to sponsors.

227
00:47:19.440 --> 00:47:27.230
TELEPHONE_USER: There has identified some general best practices for meetings between FDA and sponsors, and I will speak to some of these.

228
00:47:27.350 --> 00:47:36.449
TELEPHONE_USER: However, this is in no way an exhaustive list, and I'm sure both FDA and my industry colleagues will add to this discussion throughout the day.

229
00:47:36.820 --> 00:47:42.040
TELEPHONE_USER: First, I would like to describe some best practices for meetings relating to FDA.

230
00:47:43.680 --> 00:47:50.520
TELEPHONE_USER: So FDA should provide clear information to sponsors about potential product or development issues.

231
00:47:51.130 --> 00:47:53.289
TELEPHONE_USER: especially major issues

232
00:47:53.620 --> 00:48:14.020
TELEPHONE_USER: as early in development or throughout development as possible. This facilitates industry's ability to consider alternative approaches prior to incurring heavy investments, or at an inopportune time, such as at the close of a clinical trial or right before filing a submission such as an NDA

233
00:48:16.860 --> 00:48:32.449
TELEPHONE_USER: when conducting a meeting or providing written responses. FDA should ensure that sufficient FDA representation with decision-making authority, are present, or have contributed, reviewed written responses to promote alignment on FDA Feedback, provided

234
00:48:33.050 --> 00:48:35.329
TELEPHONE_USER: this helps avoid changes.

235
00:48:35.710 --> 00:48:37.970
TELEPHONE_USER: The FDA advice later

236
00:48:38.610 --> 00:48:41.970
TELEPHONE_USER: and provides more stability for industry decisions.

237
00:48:44.310 --> 00:48:52.769
TELEPHONE_USER: FDA meeting PDUFA meeting management goals, as were just described, is imperative to industry. To ensure that we meet our development milestones.

238
00:48:53.240 --> 00:49:13.569
TELEPHONE_USER: sponsors, map development program milestones based on PDUFA timelines. And when FDA meetings are delayed or input is delayed, sponsors may need to slow down product development or make program adjustments or decisions later. Really, perhaps, you know.

239
00:49:13.770 --> 00:49:17.629
TELEPHONE_USER: implicating our development timelines or our decisions.

240
00:49:17.920 --> 00:49:34.940
TELEPHONE_USER: Sponsors appreciate FDA granting the same meeting format as is requested. For instance, if industry requests a virtual or face-to-face meeting. If FDA converts this to a written response, the ability for discussion with the FDA is greatly decreased.

241
00:49:36.200 --> 00:49:42.980
TELEPHONE_USER: Next, I'd like to talk about some experiences that we have had with best practices related to sponsor conduct.

242
00:49:44.280 --> 00:49:53.899
TELEPHONE_USER: A sponsor should be aware of and follow all available FDA regulations, guidances, and any communicated best practices surrounding FDA meetings.

243
00:49:54.060 --> 00:50:00.010
TELEPHONE_USER: This ensures. Interactions with FDA are meaningful, and industry is not wasting FDA's time.

244
00:50:00.350 --> 00:50:04.220
TELEPHONE_USER: Meeting requests and packages should be tailored to FDA needs.

245
00:50:04.280 --> 00:50:08.709
TELEPHONE_USER: Effie only gets the information that a sponsor provides.

246

00:50:08.750 --> 00:50:15.610
TELEPHONE_USER: and therefore the information needs to be succinct, yet sufficient to ensure FDA can provide valuable feedback.

247
00:50:16.320 --> 00:50:22.200
TELEPHONE_USER: Clear, transparent communication is essential for conducting effective FDA meetings or written feedback

248
00:50:22.540 --> 00:50:32.749
TELEPHONE_USER: in a face-to-face or virtual meeting. If this is conducted, sponsors should ensure that they understand FDA's feedback and confirm this understanding. During the meeting.

249
00:50:32.790 --> 00:50:41.200
TELEPHONE_USER: Similarly, FDA should have interactive discussions and ask clarifying questions as needed, and clearly explain their position as appropriate.

250
00:50:41.590 --> 00:51:01.469
TELEPHONE_USER: We have 30 seconds remaining. Thank you very much. Finally, industry appreciates FDA, taking the time to discuss off camera as needed during a virtual face-to-face or teleconference meeting, and similarly appreciates FDA allowing sponsors to do the same. This practice saves time and ensures agreement amongst individual parties.

251
00:51:01.560 --> 00:51:10.569
TELEPHONE_USER: With that. I'd like to thank FDA for providing me the ability to contribute to this conversation, and I look forward to delving more deeply into these issues throughout the day.

252
00:51:11.480 --> 00:51:12.380
TELEPHONE_USER: Right.

253
00:51:12.530 --> 00:51:36.480
TELEPHONE_USER: thank you. To both of you, Sande and Allison, for your responses to this question. And now I'd like to open this up to conversation and discussion amongst all the panelists, and I think I'm going to move over to that other mic, so I can see you more easily. But while I do that, if any of you would like to get started

254
00:51:36.550 --> 00:51:39.069
TELEPHONE_USER: with any discussion or comments.

255
00:51:59.090 --> 00:52:10.280

TELEPHONE_USER: I just had. One question of one of the items that you brought up is you've brought up a sufficient FDA representation to be either at the meetings or have, I'm assuming.

256
00:52:10.440 --> 00:52:16.430
TELEPHONE_USER: have had some input into the minutes or the

257
00:52:18.370 --> 00:52:25.349
TELEPHONE_USER: response, only that you may have received is that, are you finding that there's that that hasn't happened, and maybe the decisions

258
00:52:25.360 --> 00:52:32.240
TELEPHONE_USER: that get made? Maybe when you either submit an application. Whether it be an IND NDA BLA

259
00:52:32.310 --> 00:52:38.029
TELEPHONE_USER: that that hasn't. That representation has been has obviously been shown.

260
00:52:38.240 --> 00:52:40.010
TELEPHONE_USER: When you get a decision.

261
00:52:40.100 --> 00:53:00.650
TELEPHONE_USER: I just want to make sure I'm capturing, because that is something that we'll need to address on our side. Yeah, maybe I can start. And then my industry colleagues can add. So what we're hoping for when we meet with FDA is to have clear advice so that we can move forward in our development. And sometimes

262
00:53:00.780 --> 00:53:11.330
TELEPHONE_USER: our thinking is, and perhaps this is incorrect. If the right people at FDA aren't actually reviewing our packages and or are in the meetings.

263
00:53:11.330 --> 00:53:33.360
TELEPHONE_USER: we might get a piece of advice that is later changed by FDA. And so we, of course, rely on this advice to move forward in our development plan, and if, then, FDA is giving us different advice in the future that really can delay and or cause a lot of internal discussion with industry if that were to happen.

264
00:53:33.360 --> 00:53:50.209
TELEPHONE_USER: So. The suggestion, in fact, is to have the right people looking at our information, and therefore providing as accurate as

possible. I understand things change, but as accurate as possible advice back to industry, so that we can then follow that advice.

265
00:53:52.470 --> 00:53:53.480
TELEPHONE_USER: Thank you.

266
00:53:57.720 --> 00:54:00.630
TELEPHONE_USER: Other comments, questions among the panelists.

267
00:54:03.610 --> 00:54:05.030
TELEPHONE_USER: Maybe I could. Just.

268
00:54:05.110 --> 00:54:08.339
TELEPHONE_USER: Bill. This is like, I'm Lisa Dow from J and J.

269
00:54:08.897 --> 00:54:13.460
TELEPHONE_USER: On occasion. We've had situations, and I think it.

270
00:54:13.640 --> 00:54:20.279
TELEPHONE_USER: It's particularly when we're looking across disciplines. And you sort of maybe a CDRH and a

271
00:54:20.320 --> 00:54:40.830
TELEPHONE_USER: a CDER division. Or maybe now we're in the new digital space where we're trying to get a co-a expert or something like that. So we're really looking, maybe beyond just the normal review team. That's really where we may find ourselves to be a bit challenged in trying to get integrated advice in a timely fashion without having to

272
00:54:40.830 --> 00:54:54.900
TELEPHONE_USER: engage in another whole series of interactions to try to get advice on a program. So I think we try to do our best to make sure we invite the right folks to attend the meetings, but maybe we're not always sure who the right ones

273
00:54:54.950 --> 00:55:03.310
TELEPHONE_USER: are to attend, particularly as we move into the new coas, etc, and knowing how to engage when to engage, making sure, we have the right input at the right time.

274
00:55:03.330 --> 00:55:11.619
TELEPHONE_USER: That does lead to some delays on our part. If we're if we're getting that advice, a few cycles later, as we have to request additional engagements

275
00:55:12.370 --> 00:55:13.230
TELEPHONE_USER: to help.

276
00:55:13.620 --> 00:55:14.686
TELEPHONE_USER: Thank you.

277
00:55:16.830 --> 00:55:22.140
TELEPHONE_USER: So this is Germany. And so to kind of

278
00:55:22.780 --> 00:55:50.939
TELEPHONE_USER: provide a scenario. It also depends on how and what you identify in the package and in your meeting. So if that is clear to us, then you know we engage the right consultants from the other parts of the agency as needed. And then you get you know what you need. So in some ways it also depends on you know how it is identified, and how clear your questions are, or how clear your package is.

279
00:55:51.600 --> 00:55:52.300
TELEPHONE_USER: Thanks.

280
00:56:00.000 --> 00:56:04.220
TELEPHONE_USER: Other thoughts, reactions, comments, questions.

281
00:56:10.170 --> 00:56:19.330
TELEPHONE_USER: Good morning. Everyone. I'm Alex May, from CSLE Behring just sort of along those lines we found. It's a best practice for industry sort of along the lines of the quality of questions.

282
00:56:19.460 --> 00:56:36.780
TELEPHONE_USER: It's really a best practice that after you receive those preliminary responses from FDA, make sure the clarification questions that you're sending back are on time and clear. There is a such thing as a poorly constructed question, even if not a bad question. So, to help FDA give the advice that we need, we should really make sure that we're sending clear questions.

283
00:56:36.950 --> 00:56:53.750
TELEPHONE_USER: And when you get your face-to-face meeting, whether it's live or virtual, really consider bringing the questions that still need to be discussed. If the preliminary responses have already addressed the question, maybe there's no real value in sort of reiterating the response that you received. It's something that we've heard.

284

00:57:04.010 --> 00:57:05.770
TELEPHONE_USER: Okay, Alex. Yes.

285
00:57:06.040 --> 00:57:07.380
TELEPHONE_USER: yes, go for it.

286
00:57:07.950 --> 00:57:18.219
TELEPHONE_USER: One of the other comments that you had made was about how industry or sponsors appreciate FDA. Granting the format that was requested.

287
00:57:18.721 --> 00:57:28.478
TELEPHONE_USER: One thing that might be helpful for FDA to understand is what, when we're when it's an item that we can transfer to a response only or

288
00:57:28.910 --> 00:57:30.709
TELEPHONE_USER: is maybe providing

289
00:57:30.810 --> 00:57:39.880
TELEPHONE_USER: some additional information of why you think it needs to be put into a face to face meeting instead of a written response. Only because a lot of times

290
00:57:40.070 --> 00:58:00.580
TELEPHONE_USER: I'm going to be honest a lot of times industry puts in face to face for everything. We haven't not recently, but before. So it might be nice if the if there really is an interaction that you think is going to be valuable in a face to face setting versus a written response, only like maybe articulating that in the actual request.

291
00:58:00.700 --> 00:58:14.420
TELEPHONE_USER: so that we can make sure that we're understanding where you're coming from, the areas that you think we need discussion more so than in a written response. Only so that might be just a suggestion for future requests.

292
00:58:14.770 --> 00:58:43.859
TELEPHONE_USER: I think it's really helpful. I think maybe the challenge is when we get the feedback as a root response. Only we sometimes we're like, good! It's clear where we're clear. We understood where we're coming from. You don't think it requires a meeting, and then we get responses back sometimes, and then we realize, oh, there might be a disconnect, and that maybe is sort of that creates the challenge because it's clear, based on how the FDA may have responded that

293
00:58:44.040 --> 00:59:01.010
TELEPHONE_USER: our point wasn't well articulated, or you didn't understand the question. We don't understand the response. But then there isn't a mechanism at that point to actually have a conversation, and then we're back into the clarification. Then maybe it leads to another meeting. So I think that's where the challenge comes sometimes where we get the

294
00:59:01.678 --> 00:59:05.889
TELEPHONE_USER: WROs, and then don't have that opportunity to actually

295
00:59:06.170 --> 00:59:11.449
TELEPHONE_USER: work through that point. It's usually not the whole, the whole set of questions. It's really those points where

296
00:59:11.730 --> 00:59:20.339
TELEPHONE_USER: you know, actually, when we actually do get to have a conversation, we realize it's something often that we could have cleared up quite simply if we had an opportunity for a dialogue.

297
00:59:20.780 --> 00:59:23.160
TELEPHONE_USER: That's honey more to build to that

298
00:59:25.560 --> 00:59:53.350
TELEPHONE_USER: I, similar to what? Jen asked. It's very well understood, for later stage meetings like interface 2, or even a type, a or a pre-BLA, to ask for a face-to-face. But I'm curious to the thinking of the industry for asking for these meetings for pre-ind, or even a type d

299
00:59:53.350 --> 01:00:02.769
TELEPHONE_USER: any thoughts you could share as to why these sometimes come in as a face-to-face request. In-person, face-to-face requests.

300
01:00:05.720 --> 01:00:10.329
TELEPHONE_USER: I mean I can start, but I suspect there'll be other comments as well. So

301
01:00:11.630 --> 01:00:26.350
TELEPHONE_USER: 1st of all, I'm not sure. So most of us now are not asking for in-person face-to-face. We're asking for virtual meetings, whether it be a teleconference or a face-to-face virtual meeting. So I know we'll get into that. But I hope that's easier.

302
01:00:26.410 --> 01:00:52.080

TELEPHONE_USER: Secondly, it's actually really important that we get feedback that we can understand during early development as well as late development. So I can say that we've had instances where exactly what Lisa's described. You know, we get a written response. But then we have questions and have some trouble getting clarification or answers to those questions.

303
01:00:52.220 --> 01:00:53.410
TELEPHONE_USER: And so

304
01:00:54.710 --> 01:01:03.250
TELEPHONE_USER: for us, even, you know, pre-ind that type of meeting would really be helpful sometimes, just to have that discussion.

305
01:01:03.320 --> 01:01:30.799
TELEPHONE_USER: even if it's not an hour, the opportunity to have the discussion and quickly clarify, I think, would save a lot of time for everyone. You don't see what happens internally in industry. But we spend a lot of time trying to figure out what's being asked and what we should do. And so there's so much value to just having this virtual discussion to clarify. In those instances.

306
01:01:34.220 --> 01:01:48.760
TELEPHONE_USER: I know we will discuss this later, but I just want to point out that we do now under PDUFA 7 have that follow-up opportunity. So I hope that you all are taking advantage of that. If you do feel that our answers are not clear

307
01:01:56.830 --> 01:01:58.170
TELEPHONE_USER: other comments.

308
01:01:58.270 --> 01:02:26.470
TELEPHONE_USER: Questions? Yes, Alex, I guess maybe one thing I'll just add to the original question about, for instance, why, for type D to face-to-face is so helpful. And I think it's because when we have that sort of small set of questions on a narrow topic, really, the timing is critical, and a lot of the value from the type. D mechanism is that shorter timeline? And so I think a big reason why the live interaction is so useful to us is that you can get all of your questions resolved and discussed, sort of all in one loop of the request process.

309
01:02:26.590 --> 01:02:38.259
TELEPHONE_USER: and from a timing perspective. It's also something that we've heard is that type fee meetings in particular can be really useful to ask questions about other aspects of development that do not have review clocks associated with them.

310
01:02:38.260 --> 01:02:57.170
TELEPHONE_USER: and so, when you use a type D, to understand whether some other request may be granted, or some other idea might be good. It can really influence our determinal decision making and planning. So again, when we don't get the live interaction, it can sort of add some of the uncertainty in terms of some of the other things that we're planning and trying to address and explore through a type d.

311
01:03:07.350 --> 01:03:11.730
TELEPHONE_USER: are there questions, comments, reactions from panelists.

312
01:03:16.090 --> 01:03:17.820
TELEPHONE_USER: Alright going once.

313
01:03:18.140 --> 01:03:19.250
TELEPHONE_USER: going twice.

314
01:03:20.530 --> 01:03:21.416
TELEPHONE_USER: All right.

315
01:03:22.040 --> 01:03:29.050
TELEPHONE_USER: So thank you for your responses to these questions. And for this discussion on this 1st discussion topic.

316
01:03:29.250 --> 01:03:38.830
TELEPHONE_USER: We'll now take a break, and we'll reconvene promptly at 1040 for the second panel discussion topic.

317
01:03:39.060 --> 01:03:41.659
TELEPHONE_USER: Thank you, and we'll see you back here soon.

318
01:04:06.671 --> 01:04:11.238
TELEPHONE_USER: I'm sorry. Did I say the wrong time?

319
01:04:12.700 --> 01:04:32.389
TELEPHONE_USER: So yes, so we are running a little bit early on our agenda. So the 1st presentation ended early, and then this panel discussion ended early. So we had planned for this discussion, panel to end at 1020,

320
01:04:32.550 --> 01:04:42.539
TELEPHONE_USER: but because the presentation ended early, and then the panel discussion was shorter. We are running about 15 min ahead.

321
01:04:42.540 --> 01:05:09.569
TELEPHONE_USER: So we had planned for a twenty-minute break from 1020 to 1040, and in order for the meeting schedule to be predictable to those who are attending. Virtually we are going to stick with our schedule so that folks can come in and join and see the topic that they had expected to see it at specific times.

322
01:05:10.370 --> 01:05:22.480
TELEPHONE_USER: So the break is going to be longer than we had initially planned. So that's why 1040 seems like a long time. But that is the correct start time for the next panel. Discussion

323
01:05:33.680 --> 01:05:39.809
TELEPHONE_USER: to go on to the next discussion panel.

324
01:05:42.160 --> 01:05:44.699
TELEPHONE_USER: All right. So everybody ready.

325
01:05:45.390 --> 01:05:46.620
TELEPHONE_USER: Okay?

326
01:05:47.090 --> 01:05:48.145
TELEPHONE_USER: So

327
01:05:49.210 --> 01:06:06.749
TELEPHONE_USER: We had our 1st panel discussion and we had a couple of of questions come in from some of the virtual participants during that period. And so I'm just going to follow up with a couple of quick questions before we get into the second panel topic.

328
01:06:07.210 --> 01:06:19.410
TELEPHONE_USER: So the 1st question is, if a sponsor requests a meeting outside of the PDUFA timeline to schedule, does it count against the agency's performance? Goal.

329
01:06:22.640 --> 01:06:33.670
TELEPHONE_USER: Hi, I can take that one. If a sponsor requests an industry meeting outside of the timeline, it does not count against our performance goals.

330
01:06:34.330 --> 01:06:40.486
TELEPHONE_USER: Okay, thank you so I don't know if everybody heard that, but it does not count against. Okay.

331
01:06:41.385 --> 01:06:45.909
TELEPHONE_USER: The second question is in the meeting request.

332
01:06:46.110 --> 01:07:09.949
TELEPHONE_USER: We should explain why a face-to-face meeting is being requested. I know one of you mentioned that it might be helpful to articulate why, you would prefer a face-to-face as opposed to written response only. And so the question is, can you provide an example of what that might look like? What a justification or reason might look like?

333
01:07:16.040 --> 01:07:27.680
TELEPHONE_USER: Yes, I think I understood the question. So the question is, why would we ask for a virtual or face-to-face meeting versus a written response? Is that the question

334
01:07:28.715 --> 01:07:33.079
TELEPHONE_USER: how to justify it, how to justify it.

335
01:07:34.760 --> 01:07:52.350
TELEPHONE_USER: So I think that this is a question that came up in response to FDA, indicating that if they are feeling like their written response is a preliminary response, or a written response only is sufficient in answering the question.

336
01:07:52.490 --> 01:08:09.939
TELEPHONE_USER: But you all kind of responded, that you know. Sometimes you still have questions, or would like clarifications. And so the I think the question is like, how might industry go about explaining why they would like a face-to-face.

337
01:08:10.290 --> 01:08:26.500
TELEPHONE_USER: I think this was brought up because of what I said in response to that comment. So I think that one of the and this is just an idea. That is obviously we. I don't think we've many people have gotten these explanations of why, in a in a meeting request.

338
01:08:27.051 --> 01:08:47.486
TELEPHONE_USER: They prefer to have a face to face in person. Meeting versus, you know, it being changed to a written response only. But one of the areas may be where you think that discussion points may be more useful. In in a face to face arena, I guess, whether in person or virtual.

339
01:08:48.870 --> 01:09:02.150

TELEPHONE_USER: So maybe you know, if you can articulate, the areas that you feel will be will value and why you value having that those interactions like if there's somewhere, because sometimes when we get questions in a meeting request.

340
01:09:02.210 --> 01:09:15.049
TELEPHONE_USER: it's not a lot of information for us to know that there may be specific areas of concern from the sponsor side that may warrant further discussion, or they have

341
01:09:15.069 --> 01:09:19.379
TELEPHONE_USER: some other underlying items they may want to discuss.

342
01:09:19.550 --> 01:09:21.949
TELEPHONE_USER: And so we're going based upon

343
01:09:21.970 --> 01:09:36.729
TELEPHONE_USER: a very small amount of information if the background package is not part of it. So if you really, truly feel a face-to-face meeting, whether it's in person or virtual is going to be more useful to a part of the discussion.

344
01:09:36.740 --> 01:09:38.910
TELEPHONE_USER: It would be easier for

345
01:09:39.170 --> 01:10:03.950
TELEPHONE_USER: for industry to put something in that request to say we have some other, you know, some surrounding issues around questions 3 and 4 that we think would value a face-to-face interaction. And this is why I don't know if that's going to help with, maybe reducing some of the, I think what was brought up earlier, you know, needing clarification, or maybe after they receive the written response, only

346
01:10:03.950 --> 01:10:10.670
TELEPHONE_USER: they may want to have a very small conversation, just to make sure that their

347
01:10:10.780 --> 01:10:12.580
TELEPHONE_USER: no confusion

348
01:10:12.630 --> 01:10:21.589
TELEPHONE_USER: does that help? I don't know if that helps the person who brought that in. But that's kind of you've given us a little bit more information than what we have right there.

349
01:10:21.770 --> 01:10:22.810
TELEPHONE_USER: Okay.

350
01:10:23.110 --> 01:10:30.060
TELEPHONE_USER: thank you. Anybody else for that. And with that, just so we don't short.

351
01:10:30.220 --> 01:10:41.209
TELEPHONE_USER: give short shrift to our next discussion topic. I will kind of get us into our second panel discussion topic, and that is meeting requests and background packages.

352
01:10:41.763 --> 01:10:45.479
TELEPHONE_USER: So we do have 2 questions for the panelists

353
01:10:45.810 --> 01:10:52.649
TELEPHONE_USER: they are. Are there best practices in terms of the timing for submitting a meeting request?

354
01:10:52.950 --> 01:10:56.659
TELEPHONE_USER: Are there other best practices for meeting requests?

355
01:10:57.340 --> 01:11:03.770
TELEPHONE_USER: Then the second question is, are there best practices for preparing and submitting a background package?

356
01:11:04.060 --> 01:11:08.180
TELEPHONE_USER: Are there thoughts or perspectives regarding the current best practices

357
01:11:08.220 --> 01:11:12.670
TELEPHONE_USER: for number of questions or issues to include in the background package.

358
01:11:13.020 --> 01:11:18.650
TELEPHONE_USER: And so once again, I'd like to start with 5 min for FDA

359
01:11:18.730 --> 01:11:29.750
TELEPHONE_USER: and Pam. I think you are going to lead us off on this one if you'd like to get started. Yeah, I'm going to start talking about the best practices for timing on meeting requests.

360

01:11:30.010 --> 01:11:56.210
TELEPHONE_USER: I want to start out. And this might kind of cross over into the next topic. But FDA puts a lot of stuff out on the Internet. We have a lot of guidances, lots of publicly available information. And one of the 1st things we would hope sponsors do is take a look at that publicly available information and see if any of that information helps answer questions.

361
01:11:56.290 --> 01:12:17.510
TELEPHONE_USER: So please utilize the information that's out there. A lot of times we do receive questions that can be answered via guidance, and so to effectively answer and manage our meetings. It's really helpful if you take a look at what's already publicly out there.

362
01:12:17.600 --> 01:12:23.579
TELEPHONE_USER: Another thing I want to talk about is specific to the timing.

363
01:12:23.980 --> 01:12:52.130
TELEPHONE_USER: Sponsors should really be aware of where they are in their development program and assess and evaluate what meetings are available to them at that point in time. So if you're in a pre-ind phase, you shouldn't be requesting an end to phase 2 meeting. You should really have knowledge of your product, know where you are, and know what meetings are applicable. And so I think that's

364
01:12:52.130 --> 01:13:15.630
TELEPHONE_USER: really a good best practice is to know what meetings are available. There's documentation out there for the types of meetings that should be submitted at specific times during your development. For example, for an end to phase 2 meeting. We would expect you to have data from your phase, 2 trials to move forward into phase. 3.

365
01:13:17.260 --> 01:13:22.609
TELEPHONE_USER: Another thing is communicating with the rpm. Aligned with your product.

366
01:13:23.431 --> 01:13:35.358
TELEPHONE_USER: A lot of times if there are. If there are questions about what meetings you can request, such as, is it time for end of phase? 2 meeting.

367
01:13:35.770 --> 01:13:59.809
TELEPHONE_USER: Please reach out to your RPM. They can always help navigate those waters, and I think that's a really good best practice, and in addition to that, they can also help. It's helpful to us if we know you're coming in for end of phase 2 meeting. And this is most

important, I think when you're requesting a type, a meeting, if you reach out to the RPM and say.

368
01:14:00.010 --> 01:14:09.300
TELEPHONE_USER: we're going to be requesting a meeting. It's great for us to know that that's coming in. Given the very short timeline for scheduling type a meetings.

369
01:14:10.350 --> 01:14:35.289
TELEPHONE_USER: Finally, when you do send in your meeting request you should be prepared to submit your meeting package in the timelines expected. So a lot of times people get very excited and want to submit their meeting request early, but then aren't ready with their meeting package. And so that causes a little bit of an issue for us.

370
01:14:35.340 --> 01:14:40.040
TELEPHONE_USER: So just be prepared. When you send in your meeting request.

371
01:14:40.270 --> 01:14:47.210
TELEPHONE_USER: make sure that you're ready to go ahead and submit your meeting package with the associated timelines.

372
01:14:47.410 --> 01:14:53.040
TELEPHONE_USER: And finally, one thing that's a little bit new in this last PDUFA is

373
01:14:53.300 --> 01:15:19.829
TELEPHONE_USER: face-to-face. Meetings have gone virtual and in person, and as an RPM, we have noticed that a lot of the requests that come in sometimes don't clarify whether you would want a in-person or virtual, and I think it's always helpful if you provide us that information, because often an RPM will have to reach out and ask the question. And so if it's provided in advance, it really helps

374
01:15:19.890 --> 01:15:24.310
TELEPHONE_USER: streamline the evaluation of those meeting requests that come in.

375
01:15:25.037 --> 01:15:28.640
TELEPHONE_USER: Those are all the topics that I had to cover, so

376
01:15:28.830 --> 01:15:30.349
TELEPHONE_USER: I'll turn it back to you.

377
01:15:30.470 --> 01:15:57.909
TELEPHONE_USER: Thank you. Other FDA panelists. Would you like to add? Yes, I just wanted to add a little bit more about the timing, especially for interact meetings. Paul mentioned this. These are very specific meetings for a particular stage of development, such that you know you should have identified your product and indication, but not have

378
01:15:57.910 --> 01:16:25.000
TELEPHONE_USER: gone so far along in your Cmc. And pharmtax, you know some proof of concept is good, but if you have defined your manufacturing process, or if you have definitive safety studies planned for your toxicology, then you are a little far gone along, you know, and you would be more ready for a pre-ind meeting.

379
01:16:25.581 --> 01:16:38.630
TELEPHONE_USER: I do want to emphasize. What Pam said about interface meetings? these are milestone meetings, and we usually get one

380
01:16:39.228 --> 01:16:46.099
TELEPHONE_USER: per study. They should not be discipline specific. These are multidisciplinary meetings.

381
01:16:46.569 --> 01:17:14.190
TELEPHONE_USER: In our experience. We do find sponsors to be very eager. We had one example recently, where we had an end of phase. One happen in November, and in February we got a request for an end of phase 2 meeting. So we didn't deny the meeting time to wrap up. Okay, we didn't deny we converted that to another meeting form. Type, rather. But

382
01:17:14.300 --> 01:17:16.099
TELEPHONE_USER: yeah, timing is important.

383
01:17:16.370 --> 01:17:19.590
TELEPHONE_USER: Right? Thank you. Thank you for your responses

384
01:17:19.780 --> 01:17:29.879
TELEPHONE_USER: and industry. If you would like to take 5 min also to respond to these questions, sure, is Elisa Dad again going to make some comments?

385
01:17:29.880 --> 01:17:55.210
TELEPHONE_USER: So, as we said that meetings are very important to industry, this is where we really want to work with the agency to make sure that we are putting together the best development programs we can to try to successfully bring our medicines to patients, and they do take a

tremendous amount of time and resource on our part to put together the appropriate briefing documents, and of course, to schedule the meetings as well.

386
01:17:55.570 --> 01:18:00.680
TELEPHONE_USER: We know that we are guilty of asking lots of questions and putting lots of information in the brazing books.

387
01:18:00.690 --> 01:18:20.999
TELEPHONE_USER: partly because, particularly at milestone meetings. This is our chance to ask lots of questions and make sure we're on the right paths. But as industry folks, it's important that we are mindful of the information that is available, not ask questions that are easily found in guidances, and really make sure that our questions are focused on the information that's most important for us to get input into.

388
01:18:21.860 --> 01:18:29.130
TELEPHONE_USER: We want to make sure that you know in that light it would be helpful for us learning more from

389
01:18:29.280 --> 01:18:39.099
TELEPHONE_USER: the FDA. What does good look like? What is just the right amount of information? Because sometimes we think we're good. But maybe we're not, and vice versa.

390
01:18:39.710 --> 01:18:53.539
TELEPHONE_USER: You did make a point of him about the Rpms. And I just wanted to highlight that sometimes it's really hard to get on Rpms. We will get responses eventually. But there is a lot of variability. I'll be 100% honest with you.

391
01:18:53.590 --> 01:19:14.770
TELEPHONE_USER: You wish it's sort of like calling the credit card company or the or something like that, and you never get a human. We love to be able to have that quick clarifying, and sometimes we can, sometimes we can't. So I think that's just something that is style and workload dependent. But it is sometimes hard to get a hold of our project managers.

392
01:19:17.500 --> 01:19:41.990
TELEPHONE_USER: I would like to just talk a little bit about the best practice for timing. We know it's really important, as I mentioned earlier, around having the right disciplines at the table. So it's important that when we, making our meeting requests that we do spend some time identifying who from the FDA, we believe, is the most important. I do think there's a little bit of uncertainty as we come to these new meaning forums.

393
01:19:41.990 --> 01:19:52.829
TELEPHONE_USER: You have new coas that are standing up. When do we request those who do we request? How do we do that? I think there's a little bit of learning that we all will need to get through together to understand the best mechanism for doing that.

394
01:19:53.340 --> 01:20:20.440
TELEPHONE_USER: We also recognize that when we put together a meeting request we're putting in questions, there's not a lot of I would call it appropriate Wiggle room for us to change those questions dramatically from the time of the meeting request to the actual briefing book, so we should, as sponsors, really be kind of clear where our positions are. What are we really asking for at the time of putting the meeting request together so that we're, you know it's not helpful to recognize

395
01:20:20.600 --> 01:20:35.819
TELEPHONE_USER: in that process between having a meeting granted and the time that you're putting your briefing book in that you have to ask a whole new question with a whole bunch of new disciplines invited. This is not going to work for the FDA, and we have to be respectful of that. So having our homework sort of done is really important

396
01:20:36.300 --> 01:20:49.460
TELEPHONE_USER: and just tactically, you've heard about the type D meetings, and it is important to note. The briefing book has to go in with those type of meetings that's new. It's something we've learned as we've experimented with the type D meetings this year.

397
01:20:53.140 --> 01:21:01.980
TELEPHONE_USER: one thing has not been mentioned, particularly at milestone meetings, like an end to phase 2 meeting. It is possible for us, as sponsors to

398
01:21:01.980 --> 01:21:24.680
TELEPHONE_USER: ask for 2 different meetings. So you could have a meeting, for example, if something's not on critical path to get all your clinical development questions laid out as an example. But perhaps your Cmc. Questions, if you have a lot of questions, can go as a separate meeting request. If it's not on critical path. I think that helps with the volume and the scope of these briefing books, and makes them a little bit more digestible for both sides to handle.

399
01:21:25.340 --> 01:21:28.509
TELEPHONE_USER: So perhaps we'll stop and see if we want to get into a dialogue.

400
01:21:28.810 --> 01:21:35.379
TELEPHONE_USER: Sure. Yeah, would anyone else from industry like to add to that before we go into the dialogue.

401
01:21:37.490 --> 01:21:39.080
TELEPHONE_USER: Okay? Great.

402
01:21:39.550 --> 01:22:01.930
TELEPHONE_USER: Okay? So both of you kind of commented on a briefing package. And one question that came in was that I'll ask now, just because it's, I think, a quick question that's related to what you all were talking about, and that is, is there a limit to the number of pages for a briefing package.

403
01:22:04.140 --> 01:22:06.805
TELEPHONE_USER: No, okay.

404
01:22:09.890 --> 01:22:10.560
TELEPHONE_USER: it's

405
01:22:11.710 --> 01:22:29.280
TELEPHONE_USER: yes. For interact. It is 50 pages. For other meetings. Our best practice is, you know, we say something between 100 150, if possible, but anything over

406
01:22:29.370 --> 01:22:49.429
TELEPHONE_USER: 300 200 5,300 is considered voluminous and will be hard to review. So this is in OTP. In CBER. We had a couple years ago. We had interactions with sponsors, and they described some of their pain points

407
01:22:49.430 --> 01:23:16.650
TELEPHONE_USER: and based on that, we drafted a resource called interactions with OTP, and in that we've mentioned each of the meeting type and kind of given a brief background about what each meeting type is, what should be in the package for some of the earlier meetings like interact and pre-ind. We've mentioned what type of questions are considered to be reasonable for the stage of development.

408
01:23:16.650 --> 01:23:30.609
TELEPHONE_USER: So that resource also talks about meeting packages. It's typical for cell and gene therapy products. But some of it is general enough for other products, too.

409
01:23:31.110 --> 01:23:45.460

TELEPHONE_USER: Thank you, Lisa, did you? I would just mention that's probably a CBER practice and not necessarily a CDER. So pages are not limited and things of that nature with CDER products.

410
01:23:49.020 --> 01:23:56.819
TELEPHONE_USER: yeah, I wanted to follow up on the earlier comment about availability and responses from Rpms.

411
01:23:57.676 --> 01:23:59.863
TELEPHONE_USER: So I would encourage

412
01:24:00.530 --> 01:24:05.519
TELEPHONE_USER: sponsors and applicants if you don't receive a response from

413
01:24:05.560 --> 01:24:28.819
TELEPHONE_USER: the assigned or aligned RPM. Please reach out to their chief the chief's names. Information are all provided on our public website. You can access that and see which chiefs are aligned with which review divisions. So again, I would really encourage you to reach out if you're not getting a response in appropriate time from your RPM,

414
01:24:29.800 --> 01:24:30.560
TELEPHONE_USER: thank you.

415
01:24:31.700 --> 01:24:53.769
TELEPHONE_USER: All right. Thank you for your responses. To those questions. Other. Yes, I wanted to add, for CBER OTP, we have a common email that is, OTP rpms@fda.hs.gov and people can reach out. Most of our Rpms are very responsive. But in case they are out for

416
01:24:54.482 --> 01:25:03.470
TELEPHONE_USER: out of office or something, then, you know, we get emails to this common that goes to all the leadership in the project management group.

417
01:25:04.914 --> 01:25:11.322
TELEPHONE_USER: Alison, yeah, yeah. Maybe just a comment. And then a question. So in regards to the briefing books,

418
01:25:11.990 --> 01:25:28.819
TELEPHONE_USER: I think one of the things at least bear tries to do is we try to put things in appendices so that the main content of what we're asking and information is up front. But then the kind of supporting documents are in appendices. I hope that's a good practice.

419
01:25:29.010 --> 01:25:39.420
TELEPHONE_USER: And then, secondly, in regards to contacting FDA. At least, my understanding is that there's no longer contact information on HHS.

420
01:25:39.630 --> 01:25:42.790
TELEPHONE_USER: And so maybe a question as to

421
01:25:43.287 --> 01:25:46.279
TELEPHONE_USER: is that true? And why is that

422
01:25:46.650 --> 01:26:00.020
TELEPHONE_USER: so? I can't comment on HHS. But on our divisional websites, at least in OD. There's a tab at the bottom that provides you to the chiefs aligned with that division.

423
01:26:00.628 --> 01:26:05.910
TELEPHONE_USER: On each of the divisional websites. That is available.

424
01:26:09.010 --> 01:26:14.050
TELEPHONE_USER: Don't know if folks have anything else regarding HS. On the panel.

425
01:26:17.320 --> 01:26:21.759
TELEPHONE_USER: Other comments? Questions on this topic.

426
01:26:22.650 --> 01:26:23.420
TELEPHONE_USER: Yes.

427
01:26:24.914 --> 01:26:30.989
TELEPHONE_USER: I guess from my perspective, I'm looking here at the best practices for the questions. And I,

428
01:26:31.160 --> 01:26:42.769
TELEPHONE_USER: you know, as sponsors, we try to be very thoughtful about the questions that we're asking and making sure that we can get those questions covered in the timeframe of the meeting. But I I may be a question to the agency is

429
01:26:43.220 --> 01:26:50.939
TELEPHONE_USER: in your experience. Are there maybe too many questions or reason that something is converted to a WRO versus

430
01:26:51.580 --> 01:26:52.130
TELEPHONE_USER: it's

431
01:26:52.150 --> 01:26:55.010
TELEPHONE_USER: in person or face to face me, or virtual meeting

432
01:26:55.560 --> 01:27:00.599
TELEPHONE_USER: like, are people or sponsors asking too many questions. And that's 1 of the reasons that you

433
01:27:00.770 --> 01:27:02.100
TELEPHONE_USER: make that decision.

434
01:27:03.267 --> 01:27:10.990
TELEPHONE_USER: I don't think that that's a reason why that people convert to WRO. I think a lot of the divisional practices.

435
01:27:11.559 --> 01:27:16.609
TELEPHONE_USER: Have started to go back to sponsors and tell them to

436
01:27:16.880 --> 01:27:18.780
TELEPHONE_USER: slim down those questions.

437
01:27:18.860 --> 01:27:22.080
TELEPHONE_USER: I think that most divisions have started that practice

438
01:27:22.130 --> 01:27:36.289
TELEPHONE_USER: where they tell them they need to reduce the number of questions, and whether it's a face-to-face in person, virtual or a written response, only they're really trying to slim down the amount of

439
01:27:36.290 --> 01:27:53.579
TELEPHONE_USER: questions they have to answer, because regardless if it's a written response only, or a face-to-face meeting, the amount of questions is going to take you the same amount of time. I mean, if it's 20 questions, it doesn't matter. Usually we have face-to-face meetings.

440
01:27:54.290 --> 01:27:57.120
TELEPHONE_USER: Once we send out the preliminary comments.

441
01:27:57.530 --> 01:28:01.580

TELEPHONE_USER: Industry is saying, oh, we only want to focus on questions. 3, 4, 5,

442
01:28:01.992 --> 01:28:07.259
TELEPHONE_USER: so we were already reducing it back then, or to that when we do the face to faces

443
01:28:07.300 --> 01:28:09.739
TELEPHONE_USER: the right response, only

444
01:28:09.770 --> 01:28:14.519
TELEPHONE_USER: it's just as hard for us to work on 20 questions

445
01:28:14.920 --> 01:28:26.569
TELEPHONE_USER: regardless of the format it is in I can see if you had to discuss all 20 questions at a face to face meeting. It is going to bite into some of the time, but

446
01:28:26.740 --> 01:28:42.120
TELEPHONE_USER: I don't think that we have a lot of experience with, or have had, a lot of experiences where people haven't gotten this preliminary comments and are reducing that number regardless. But the manageable level seems to be right around 10.

447
01:28:42.240 --> 01:28:52.629
TELEPHONE_USER: I'm not gonna say that people aren't getting meetings. Granted. If they have more than 10 questions, cause we know that happens. But there are. There is that manageable level to be able to.

448
01:28:52.680 --> 01:29:18.779
TELEPHONE_USER: I mean, I think, that I think, one of the slides that Paul mentioned. How many hours and you know how many meetings a day FDA would be having based upon the number of meeting requests we get, but that doesn't even count the pre-meetings that we have to have in order to provide answers to you. So we're not only having a meeting with you. We're having a meeting internally to be able to make sure our answers are adequate and

449
01:29:19.098 --> 01:29:23.880
TELEPHONE_USER: those do tend to. If we have too many of them. It does tend to

450
01:29:23.990 --> 01:29:25.969
TELEPHONE_USER: go too far, and

451
01:29:25.980 --> 01:29:28.320
TELEPHONE_USER: we have a hard time managing that.

452
01:29:28.400 --> 01:29:31.170
TELEPHONE_USER: Does that help. Okay, yeah.

453
01:29:31.560 --> 01:29:49.189
TELEPHONE_USER: Hi, this is Banu Karimi-Shah, I in my division. I'm surrounded by a lot of expertise here on the project management side, but I'm a clinical person, so I'm the deputy director of my division, and I go through all of the meeting requests to decide in our division.

454
01:29:49.190 --> 01:30:13.880
TELEPHONE_USER: We grant almost all of them, but how they're granted the format, the meeting type, and I will tell you that the number of questions doesn't usually influence us in our division as to whether it's granted written response only, or face-to-face, virtual or in-person. But I think the point that Jen makes is very valid. Our internal meetings, whether we issue you written responses, or we then follow up

455
01:30:13.880 --> 01:30:38.140
TELEPHONE_USER: with a meeting with you to discuss those in responses. We usually schedule our meetings for an hour, unless it's an end of phase, 2 meeting, which are some of these other milestone meetings which we internally schedule for an hour and a half. But you see, as Paul mentioned, and as Jen mentioned the number of meetings. If we have to have all of those meetings, we can't schedule every internal discussion for an hour and a half or 2 h. So we really like to

456
01:30:38.140 --> 01:30:39.920
TELEPHONE_USER: have enough

457
01:30:40.060 --> 01:31:04.479
TELEPHONE_USER: or the right amount of questions, to be able to get through those responses in an hour. So you can see where you have questions with multiple parts or multiple disciplines, that sort of bleeds over into potentially the next meeting or our ability to then a be able to schedule a meeting with the sponsor because we're still discussing internally from the last one. So I think that is

458
01:31:04.480 --> 01:31:28.799
TELEPHONE_USER: really big point that Jen also made that it's the internal discussion that needs to happen. And also to the point, I think that you made on the end to sort of get the right advice and to have the signatory weigh in. In those internal meetings. The signatory is sitting

in those meetings. If we run out of time, then it sort of impacts the signatory's ability to be able to agree with what

459
01:31:28.800 --> 01:31:51.060
TELEPHONE_USER: we tell you. And then a lot of those exchanges, even internally, have to take place in extra meetings or over email, and that can sometimes impact. You know this advice that you may be receiving, that, you know, or the quality of the advice that you may be receiving. So I think that's a very important point. Thank you. So we are at time for this

460
01:31:51.100 --> 01:31:54.880
TELEPHONE_USER: section. Did you all have just a very brief

461
01:31:55.290 --> 01:31:59.510
TELEPHONE_USER: responses. I know a couple of you lit up your mic, so I just wanted to check.

462
01:32:00.980 --> 01:32:26.250
TELEPHONE_USER: I guess mine's more of a question, and I can leave it as an open question if there's not time to answer it. But I think we've sort of been talking around this, so I'll just say I know there was a guidance, and time is escaping me, maybe within the last 6 or 12 months, where the number of questions was specified for sort of what's appropriate for a meeting request. So my question would be for our FDA colleagues whether you've sort of noticed industry responding to this guidance, whether that's sort of changed

463
01:32:26.250 --> 01:32:41.350
TELEPHONE_USER: sort of the contents of the requests that you're seeing, and I think the other part of that question is, do you think that a reduction or clarifying the ideal amount of questions has resulted in more meeting requests? Or do you think it has the potential to result in more meeting requests that would be interesting to think about.

464
01:32:45.383 --> 01:32:53.589
TELEPHONE_USER: Yeah, I don't know that we have an exact answer for that, but we will have to look at something like that, but I do know that

465
01:32:53.680 --> 01:33:11.899
TELEPHONE_USER: well, I do know. At least the majority of our meeting requests are coming in with fewer questions, and people are trying to align with the guidance. I don't know if that has impacted the amount of meeting requests we've gotten if people are doing multiple meetings. But we can look into that. Thank you

466

01:33:12.600 --> 01:33:13.050
TELEPHONE_USER: alright.

467
01:33:13.670 --> 01:33:18.949
TELEPHONE_USER: So thank you for your responses to our second panel discussion topic.

468
01:33:18.980 --> 01:33:31.209
TELEPHONE_USER: If you all don't mind just advancing the slide to the next discussion topic, so that it's on screen. So our next discussion topic is meeting management for all meeting types.

469
01:33:31.410 --> 01:33:34.959
TELEPHONE_USER: And so once again, we have 2 questions for our panelists.

470
01:33:35.844 --> 01:33:42.660
TELEPHONE_USER: The 1st question is, are there best practices for managing time agendas and meeting interactions?

471
01:33:43.250 --> 01:33:53.219
TELEPHONE_USER: And the second question is what types of trainings and or communications related to meeting management would be most useful in the future.

472
01:33:54.290 --> 01:33:59.338
TELEPHONE_USER: So once again, we'll start with 5 min for FDA and

473
01:34:01.864 --> 01:34:05.955
TELEPHONE_USER: Ramini, I think that you're going to start us off. Thank you. I'll start

474
01:34:06.630 --> 01:34:15.759
TELEPHONE_USER: So we work on the premise that it is the sponsors hour and but what we usually find is

475
01:34:15.770 --> 01:34:27.589
TELEPHONE_USER: that sometimes there is a significant time spent on presentations from sponsors, or you know.

476
01:34:27.610 --> 01:34:33.490
TELEPHONE_USER: the sponsors would bring in their PIs, or they would bring the patient advocates.

477

01:34:33.550 --> 01:34:42.040
TELEPHONE_USER: And while we absolutely love to hear from patients, and you know it. It sometimes puts

478
01:34:42.160 --> 01:34:57.760
TELEPHONE_USER: the product development in perspective. It does take up a lot of the allotted hour. So you know, we've had situations where a bulk of the hour was taken up

479
01:34:57.760 --> 01:35:17.210
TELEPHONE_USER: by the presentation or the discussion with the patient advocates, and whatever the challenges were with the program or the discussion points were both the groups. FDA and the sponsor walked away without resolving them. And you know it was back to the square one again.

480
01:35:17.210 --> 01:35:28.620
TELEPHONE_USER: We think these are very valuable. The patient perspective is very valuable, but would help if maybe they are allotted to the later half of the meeting.

481
01:35:29.002 --> 01:35:34.359
TELEPHONE_USER: Than you know up front. Whatever the challenges are, those should be discussed first.st

482
01:35:36.639 --> 01:35:37.379
TELEPHONE_USER: and

483
01:35:37.980 --> 01:35:55.756
TELEPHONE_USER: what else? It's also helpful. If once the sponsor re receives the preliminary responses. If they can write back to the Rpm and let them know what are the points they want to discuss by the order of prioritization.

484
01:35:57.525 --> 01:35:58.850
TELEPHONE_USER: And

485
01:35:59.493 --> 01:36:09.359
TELEPHONE_USER: lend the introductions in the beginning. Or you know, that that's something you know, we found through the

486
01:36:09.728 --> 01:36:21.889
TELEPHONE_USER: pandemic when we started doing telecoms. You know, to kind of forego the introductions, and when people are talking they could, you know, state who they are, and that's that we found that to be helpful.

487
01:36:22.040 --> 01:36:40.559
TELEPHONE_USER: and something else that comes up very frequently is based on the FDA response. There is a new proposal, or there is a new idea that is presented in the response that the sponsor provides to the FDA comments.

488
01:36:40.570 --> 01:36:47.929
TELEPHONE_USER: and very often, you know, the team has not had a chance to meet or to discuss this. They don't have enough time to

489
01:36:48.000 --> 01:36:53.250
TELEPHONE_USER: to vet this out, so you know a a response may not be available.

490
01:36:53.678 --> 01:36:59.121
TELEPHONE_USER: I'll stop there and see if anyone else has things to add

491
01:37:01.528 --> 01:37:04.320
TELEPHONE_USER: anyone from FDA want to add to that.

492
01:37:06.230 --> 01:37:06.790
TELEPHONE_USER: Okay.

493
01:37:07.450 --> 01:37:15.076
TELEPHONE_USER: why don't we shift over to industry, then, who would like to lead off? Get me again?

494
01:37:15.770 --> 01:37:39.910
TELEPHONE_USER: So I think many of the points that you just raised would be points that the industry as well would echo. I think it's very important for us that we do use the meeting to focus on the topics that really warrant the discussion. So we have complete alignment. There's no reason to recapitulate that in a discussion, it's just to your point focusing on those areas where we really want to have a further dialogue and

495
01:37:40.020 --> 01:37:55.299
TELEPHONE_USER: seek clarification. Those are such rich conversations. And it's so obvious when you actually are able to have those conversations, how often there's a bit of a misunderstanding or a lack of clarity of communication on our end, and perhaps a lack of

496
01:37:55.300 --> 01:38:13.660

TELEPHONE_USER: the same on your end, and by actually having the conversation. It demystifies things. It sometimes makes things much simpler, not always, but it then speaks to the richness of why we want the meetings as opposed to written response. Only because you realize that there's an opportunity there to make sure that we're all on the same page.

497
01:38:14.620 --> 01:38:24.530
TELEPHONE_USER: We agree with you around just following the best practices it's been great to do away with.

498
01:38:24.530 --> 01:38:48.180
TELEPHONE_USER: So the niceties, I guess, of those introductions, and just get right into the meeting. At the other hand, it's also really great to have some consistency. Sometimes there's all cameras off. We can't see body language. We try to make sure that we're doing our part on our end, but just actually seeing the faces and seeing the body language is really helpful. So we appreciate that when that's possible in a virtual face-to-face meeting.

499
01:38:51.960 --> 01:39:15.880
TELEPHONE_USER: one thing we didn't touch on yet is the minutes. And then, when we do ask for a new idea as we get some very strong feedback, it's very clear we have to offer an alternative proposal getting an agreement in the meeting on how to best handle that is helpful. So we walk away with the same expectation. So, for example, sometimes you'll say, submit it to us. We'll comment on the minutes, or maybe if you send it into

500
01:39:15.880 --> 01:39:29.629
TELEPHONE_USER: such and such a time we'll get back to you right away, just having that agreement between the sponsor and the FDA is really helpful, so that we know sort of when the story ends, and we have that commitment for the feedback. So that's a great thing for us to continue to try to do.

501
01:39:29.980 --> 01:39:53.949
TELEPHONE_USER: I think it's really important as sponsors, and I assume as well for the FDA that when we're done with the topic, or at the end of the meeting we recap what we think the major agreements are. So sometimes we find when you actually go back. This is like meeting 101 stuff. Right? You go back and you realize that we weren't completely aligned on something. And so, just having that discipline to go back and say, well, we think we agreed on

502
01:39:53.950 --> 01:40:00.990

TELEPHONE_USER: XY. And Z. It gives each side an opportunity to ask that last clarifying question before you hang up the phone. So we think that's super important.

503
01:40:02.980 --> 01:40:09.478
TELEPHONE_USER: I think I've said this 3 times, but I'll say it one more time is occasionally it's

504
01:40:10.100 --> 01:40:39.909
TELEPHONE_USER: We see as well prepared as both sides. Try to be. Occasionally people don't have their ducks in a row. So on a rare occasion, we've had instances where it's clear that the FDA didn't have time to pre-align on something particularly across disciplines, or maybe across CDRH with the review division, and I think occasionally on our side, although we try to prep really well, occasionally we may be on different pages. Right? So it's just important that everyone does their homework. And then

505
01:40:39.910 --> 01:40:51.389
TELEPHONE_USER: we have a chance to make sure that we're speaking on each side with one voice, so that the sponsor and or the update is not getting mixed signals, because that makes it quite difficult for both sides.

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01:40:54.090 --> 01:41:00.269
TELEPHONE_USER: think, that's probably all I want to say. Do you guys have anything to build on for this section.

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01:41:02.356 --> 01:41:06.620
TELEPHONE_USER: I could maybe add one of the things

508
01:41:06.800 --> 01:41:15.419
TELEPHONE_USER: it's kind of a 1-off, I would say, is the language that FDA uses in meetings or in written responses. In particular.

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01:41:15.650 --> 01:41:44.610
TELEPHONE_USER: I think in this culture we're very polite, and so FDA will say they suggest as an example. And so sometimes, if English is not your 1st language, or you're, for instance, not North American. A suggestion might not seem like a requirement, and so it would be helpful to be very clear. Is this a recommendation that isn't as important, or really, is it a requirement in that suggestion? So I think that's something that would be really helpful.

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01:41:47.000 --> 01:41:50.324
TELEPHONE_USER: Actually, though, just to build on Alison's point

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01:41:51.680 --> 01:41:56.019
TELEPHONE_USER: Occasionally, we know that the agency's interested

512
01:41:56.370 --> 01:42:11.290
TELEPHONE_USER: in additional information to help inform. Maybe the science behind a topic. Or maybe you begin to accumulate some experience on an endpoint or on a population or something. Right? And you may ask us to consider, including

513
01:42:11.290 --> 01:42:36.119
TELEPHONE_USER: additional data, collection or analyses, etc, in our programs. And we're not always clear when it's a suggestive nice to have exploratory versus. This is a really critical point that your program success hinges on. So if there's where possible to put the temperature on, the request would be very helpful. And then the final point is.

514
01:42:36.860 --> 01:42:54.599
TELEPHONE_USER: particularly when we get written responses, only it's not always 100% clear to us who was part of the team. So we may request. You know, all these disciplines to be involved, and if they show up in a meeting because we're actually having a meeting, then we know that they all contributed to it. I think we have to assume

515
01:42:54.750 --> 01:43:19.860
TELEPHONE_USER: that those same disciplines may have been part of a written request, only response. But we actually don't know that for sure. So is it possible just to say these disciplines were part of the conversation, just so that we know that we don't have that wonder. Well, do they actually reach out to whoever across the hall to see if they can contribute to this? I think that would just give us a little bit more clarity and demystify things a bit for us.

516
01:43:22.760 --> 01:43:23.740
TELEPHONE_USER: All right.

517
01:43:24.490 --> 01:43:33.029
TELEPHONE_USER: Thank you for those responses. I want to open it up to discussion. We kind of started getting into that, anyway, Alex.

518
01:43:33.210 --> 01:43:43.350
TELEPHONE_USER: sure, so definitely appreciated the points from FDA about how prioritizing questions and sort of the order of topics and making sure that we're focusing on what's most important to us is really important.

519

01:43:43.390 --> 01:44:07.559
TELEPHONE_USER: And I'll add that sometimes FDA will even ask us for a meeting sort of outside of the usual meeting mechanism. Sometimes. FDA, I won't call it an informal meeting. I know that's sort of a loaded phrase, but will ask us for a call, and we're happy to take the call, and you find that those calls can be really valuable, and sometimes even more valuable in a formal meeting, because you can really dig into a narrow. Maybe it's a scientific topics, just some sort of a narrow area. And for those we find it really helpful. When FDA also provides

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01:44:07.560 --> 01:44:19.300
TELEPHONE_USER: some indication of the agenda that they'd like to cover the type of questions they'd like to explore, even though it's not a formal meeting, because it allows the sponsor to prepare a bit more and make sure that we're really getting the best use out of that dialogue.

521
01:44:22.710 --> 01:44:23.540
TELEPHONE_USER: Yes.

522
01:44:25.260 --> 01:44:46.229
TELEPHONE_USER: I wanted to go back to a few comments, and I'm sure others probably want to address those as well. The 1st thing coming from the office of regulatory operations. I heard that you said, are we did to see people's faces in a in a meeting just wanted to be very clear that in a teleconference we will not turn our cameras on.

523
01:44:46.230 --> 01:45:11.259
TELEPHONE_USER: However, if we are having a virtual face-to-face meeting, it is both CBER and CDER policy that staff turn on their cameras. There could be reasons why a staff member cannot turn on their cameras. And so that wouldn't be 100%. The case we do allow for exceptions, and anything could be going on as to why they might not be able to turn on their camera. But in a virtual face-to-face we should be cameras on when we're speaking.

524
01:45:11.650 --> 01:45:13.210
TELEPHONE_USER: The second

525
01:45:13.410 --> 01:45:39.619
TELEPHONE_USER: comment I just want to make around FDA's language. We are very specific with the words that we use overly specific. So when we use the word suggest, that's our scientific, our medical opinion, we only use must when we are talking about laws, regulations, even guidances, unless it's a binding guidance. We have very few, but ect is one of them. We have very few binding guidances.

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01:45:39.620 --> 01:46:00.730

TELEPHONE_USER: but even when we're speaking as to what's in a guidance. We'll still you suggest, and you may consider, because you could come up with an alternative approach to how you handle that. And that's fine. We want to be open to alternative approaches. We don't want to stifle development in the field. And so

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01:46:00.780 --> 01:46:04.310
TELEPHONE_USER: we specifically choose those words very carefully.

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01:46:11.600 --> 01:46:13.980
TELEPHONE_USER: Thank you. Thank you. Yes, Alison.

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01:46:14.520 --> 01:46:32.489
TELEPHONE_USER: yeah, maybe also a question. So one of the things that we really appreciate in regards to timing is when we get FDA, for instance, preliminary comments as early as possible, because it allows us then to take a look at them and get back to you, for instance, as to what we want to cover and be very succinct there.

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01:46:32.530 --> 01:46:50.570
TELEPHONE_USER: My question is perhaps to FDA, in regards to do you also appreciate the same courtesy. For instance, if we could provide you a briefing book ahead of what is required. Is that helpful to you? Or is that something you don't look at until the exact timeline

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01:46:51.410 --> 01:47:11.300
TELEPHONE_USER: that's extremely helpful to us, and I know that there are requirements around meeting types. And so the briefing book isn't always due. But I think this goes back to something that you brought up earlier about, whether we grant something written responses or we grant it as a face-to-face meeting. When you see the meeting request, and, you see.

532
01:47:11.350 --> 01:47:14.209
TELEPHONE_USER: is our non-clinical study adequate to proceed.

533
01:47:14.770 --> 01:47:40.190
TELEPHONE_USER: I mean, it could be a straightforward question, but it could not be a straightforward question, and you know, in an early phase of development, we might look at that and say, like, Oh, we can handle that with written responses. But if it had the briefing book in there. I mean we do we? Do you know the people who grant the meetings? I can speak for myself, and then the people who are assigned to review as a reviewers look at those when they get them, at least do a preliminary look through.

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01:47:40.220 --> 01:48:00.380

TELEPHONE_USER: So if there's something in there that you think really does require a face-to-face discussion. That would be better explained if the briefing package was with the questions that would really help, because the meeting request questions are sometimes just really general. And I read a lot of these, and I look at these at the pre-IND time and think.

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01:48:00.540 --> 01:48:08.157
TELEPHONE_USER: yeah, this should be fine. We can just handle this with written responses. And then, you know, we get the and we get the briefing package. And I'm very

536
01:48:08.510 --> 01:48:32.749
TELEPHONE_USER: I'm very empathic to the person who said, Oh, you know, FDA grants it written responses, and we think this is good. They think it's clear. And then on the other end we get the briefing package, and we're like man. We granted this written responses. And now we're going to have to craft some really meaty and complex responses. So I think that doing that up front a reviewer, and from a clinical standpoint

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01:48:32.750 --> 01:48:52.599
TELEPHONE_USER: point would be very helpful and sort of if it can be done. I understand there are situations in which that's just not possible. But you know, especially if you really want to have one of these meetings that can be converted to a written responses only, and you are really interested in not having it be converted. That would be very helpful.

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01:48:55.380 --> 01:48:56.570
TELEPHONE_USER: Yes, Brad.

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01:48:57.880 --> 01:49:02.620
TELEPHONE_USER: I have a point about that, but also just in general. One of the things I think is important is.

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01:49:02.860 --> 01:49:30.550
TELEPHONE_USER: if you really want that in person or face to face meeting. Be thoughtful about the questions that you're asking, and make sure those are questions that you want to get answered face to face right? And that you can do that in appropriate timeframe. But I think, with respect to your comment on the WROs. You know, you guys mentioned earlier that it would be helpful for us as industry to justify to you guys why, we think that a face to face, or in person or in person meeting would be

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01:49:30.895 --> 01:49:42.629

TELEPHONE_USER: beneficial. It would help us if we understood why something was converted to a WRO and to maybe have an opportunity for some type of initial dialogue to say, Oh, wait, you know.

542
01:49:43.130 --> 01:50:01.139
TELEPHONE_USER: No, you know, we really need time with you guys to discuss this point. So you know, we can definitely do a better job, I think, as industry, and just in explaining why we need that face to face meeting or in, or virtual meeting. But I think it kind of goes a little bit both ways for us, cause it would help us

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01:50:01.150 --> 01:50:06.269
TELEPHONE_USER: sometimes interpret the response, or sometimes understand that we weren't clear, and how we asked something

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01:50:09.160 --> 01:50:35.459
TELEPHONE_USER: so for us in OTP. It is. If you've had a pre-ind for that product before we do have some that come back. You know they've had a pre-ind several years before, or they've had one, and sometimes they've just had one recently, and they still come back. So then, that you know, if we feel it's, it's been a significant period, and there is some change

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01:50:35.460 --> 01:50:42.240
TELEPHONE_USER: in the development process. Then we would grant it as maybe a written response. If

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01:50:42.240 --> 01:51:10.279
TELEPHONE_USER: you've had interactions with the office before, like they're in the form of INDs. If you've had IDS with us before, then you know that how we function. So in that case it could be a written response. Or if you're using the same product for a different indication that would still come to OTP. In that case we would most likely grant it as a written response.

547
01:51:10.870 --> 01:51:27.109
TELEPHONE_USER: I hope that helps. Thank you. Actually, one of the questions that came in is kind of related to this, and that is, that some divisions have appear to have different practices, you know, with regard to kind of meeting

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01:51:27.180 --> 01:51:39.620
TELEPHONE_USER: types and conversion and meeting management in general, and so kind of hearing you talk about kind of these different variables like, I'm wondering are those

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01:51:39.720 --> 01:51:49.070

TELEPHONE_USER: kind of part of the reasons for that, or do you do you think it's possible to standardize? Given these many variables that are in play.

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01:51:50.447 --> 01:52:05.189
TELEPHONE_USER: I would say that probably every division has their own practices, and not that it's good or bad. It depends on indications. The familiarity with the company that you're working with. You know, if this is the

551
01:52:05.530 --> 01:52:06.560
TELEPHONE_USER: 7, the

552
01:52:06.840 --> 01:52:10.869
TELEPHONE_USER: you know drug product that is you know what we call the me, too. Product

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01:52:10.920 --> 01:52:25.790
TELEPHONE_USER: that, you know, is coming in for the same indication. That's probably going to make us lean towards more of the written response. If it's something that we can convert. You know, I don't think it's easy to go across 28 clinical divisions with

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01:52:26.621 --> 01:52:29.330
TELEPHONE_USER: on hundreds of different indications

555
01:52:29.380 --> 01:52:45.670
TELEPHONE_USER: and issues that are surrounding those indications and become so standardized, at least in at least in O. And DII don't. I don't know how. I'm sure CBER probably has some practices that they use, but there is, you know, there's a hope that we can get to some.

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01:52:45.920 --> 01:53:02.240
TELEPHONE_USER: maybe a smaller scale of being somewhat consistent. I don't know that it can be across the board like if you ask this question, or you have this type of drug, or you're you got this answer from, you know you got the written response only from this division. This division is going to do the same thing. I don't think that that's

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01:53:02.781 --> 01:53:05.669
TELEPHONE_USER: possible, because of all these variabilities.

558
01:53:06.860 --> 01:53:18.870
TELEPHONE_USER: we would we could try. I don't know that how successful it's gonna be, but and I understand the frustration that you know, if

you're a company that works with multiple divisions, and you know where you're not getting the same

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01:53:18.900 --> 01:53:29.409
TELEPHONE_USER: types of responses, or you know conversions or things of that nature. It can be confusing as to why you're, you know, having those issues. But we are.

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01:53:29.440 --> 01:53:33.329
TELEPHONE_USER: There are reasons behind them. And there's usually

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01:53:33.735 --> 01:53:43.489
TELEPHONE_USER: some of them are complex reasons. Some of them are very simple. I don't know if anybody from L and D wants to change, say anything different. CBER.

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01:53:46.250 --> 01:53:57.939
TELEPHONE_USER: Part of it is also organization, the way and D and CDER are organized compared to how CBER are organized. We are organized by products.

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01:53:58.525 --> 01:54:07.624
TELEPHONE_USER: And Wendy is by indication. So you know, it's not really an apples to apples comparison.

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01:54:09.100 --> 01:54:14.520
TELEPHONE_USER: Yeah. And that actually kind of relates to another question that came up, and that is

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01:54:14.550 --> 01:54:18.570
TELEPHONE_USER: that you know, in some cases sponsors might have a single

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01:54:18.600 --> 01:54:22.670
TELEPHONE_USER: product. That has multiple indications.

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01:54:22.900 --> 01:54:26.439
TELEPHONE_USER: And across multiple review divisions.

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01:54:26.700 --> 01:54:34.270
TELEPHONE_USER: And so it earlier talked about having kind of meetings for specific

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01:54:34.320 --> 01:54:39.349

TELEPHONE_USER: drug product and indication and not across multiple indications.

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01:54:39.745 --> 01:54:44.759
TELEPHONE_USER: In some cases sponsors might feel like the question is really agnostic to

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01:54:44.780 --> 01:54:47.599
TELEPHONE_USER: indication. It might

572
01:54:47.720 --> 01:55:00.210
TELEPHONE_USER: question pharmacology or toxicology might pertain to all of the indications for a single product. And do you have any advice on how sponsors might

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01:55:00.330 --> 01:55:02.060
TELEPHONE_USER: ask those kinds of questions?

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01:55:02.790 --> 01:55:10.550
TELEPHONE_USER: Yeah, I mean, we have the mechanism to provide advice over multiple disciplines.

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01:55:11.032 --> 01:55:17.150
TELEPHONE_USER: For a question that you know, for a question that's geared at, you know, many indications.

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01:55:17.290 --> 01:55:21.910
TELEPHONE_USER: Erm, I just think it's really important that if you have that

577
01:55:22.020 --> 01:55:39.790
TELEPHONE_USER: type of. If you're going to have that type of meeting request, or if you have those types of questions, it is really imperative that you speak with an Rpm. 1st on how you should submit those questions so that they're aware and can guide you to the appropriate path

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01:55:39.950 --> 01:56:01.249
TELEPHONE_USER: a lot of times we'll have a combined meeting where, especially if it spans multiple divisions in OD, we'll have an OND division. Take a lead and then have representation from those other groups that will be seeing those indications when they come in.

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01:56:01.350 --> 01:56:16.240

TELEPHONE_USER: So I think it's just really good to communicate with us, if that's the hope is to have one meeting for multiple indications, at least in O. And D reach out and discuss with us the best practice to do. You know how to facilitate that.

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01:56:16.670 --> 01:56:23.400
TELEPHONE_USER: One other thing I wanted to mention, too, and this has come up. A few times today is

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01:56:24.117 --> 01:56:33.359
TELEPHONE_USER: we do encourage sponsors to provide us information on who they believe should attend the meeting.

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01:56:33.550 --> 01:56:57.050
TELEPHONE_USER: But ultimately, when the meeting package comes in and the meeting request that assessment is done by the review division, and hopefully we do it well and get the right people in the room. So you know, don't be surprised if there are additions or folks that you've requested that maybe don't attend, because that assessment is done when we get that information in

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01:56:57.680 --> 01:57:06.180
TELEPHONE_USER: right. Thank you. And we are at time for this segment. So I'd like to move on to our next discussion topic.

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01:57:06.260 --> 01:57:11.629
TELEPHONE_USER: So if you all can advance the slide so folks can see it on screen.

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01:57:11.790 --> 01:57:18.000
TELEPHONE_USER: Erm. The next discussion topic is meeting minutes and follow up opportunities.

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01:57:18.130 --> 01:57:22.920
TELEPHONE_USER: And so once again we have 2 questions for our panelists.

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01:57:22.980 --> 01:57:27.720
TELEPHONE_USER: The 1st question is, are there best practices for taking meeting minutes

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01:57:27.940 --> 01:57:32.350
TELEPHONE_USER: are the best practices for the discussion and approval of meeting minutes?

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01:57:32.810 --> 01:57:39.080
TELEPHONE_USER: And then the second question is, are there best practices for follow-up clarification opportunities?

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01:57:39.570 --> 01:57:49.510
TELEPHONE_USER: And so once again, we'll start with 5 min for FDA and Romani. Are you starting off? Great. Thank you.

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01:57:49.520 --> 01:58:06.929
TELEPHONE_USER: So I'll start with meeting minutes. What we have to remember is that meeting summaries. They are not a transcription of the discussion. They are a capture of agreements, disagreements, and action items.

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01:58:07.010 --> 01:58:11.289
TELEPHONE_USER: As someone mentioned earlier. It's very helpful if

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01:58:12.183 --> 01:58:19.319
TELEPHONE_USER: there is a summary, either at the end of each question, or at the end of the meeting.

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01:58:21.450 --> 01:58:36.590
TELEPHONE_USER: excuse me so that you know each group walks away with you know the what the discussion, a clear understanding of what the discussion was. We often get requests to change minutes

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01:58:36.740 --> 01:59:00.119
TELEPHONE_USER: or meeting summaries, but these are usually for saved, for you know, unless we make a mistake in how it was captured. But usually the requests are for clear transcription of the discussion, which we don't do, and I'll turn it to the others.

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01:59:04.410 --> 01:59:07.110
TELEPHONE_USER: Anyone else from FDA would like to add to that.

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01:59:09.030 --> 01:59:10.690
TELEPHONE_USER: Yes, okay.

598
01:59:11.392 --> 01:59:23.019
TELEPHONE_USER: All right. Well, in that case, why don't we move on to industry? And if you would like to. Oh, I'm sorry. Did you have something you wanted to say?

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01:59:23.630 --> 01:59:28.170

TELEPHONE_USER: Well, I guess. Are we gonna go through the second question.

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01:59:29.240 --> 01:59:47.449
TELEPHONE_USER: Oh, I'm sorry. Yeah. That prompt was invited. Oh, I'm sorry I didn't. Oh, okay, so, please. I thought it was just for the 1st part. No, no, no, so I'm going to take on the best practices for discussion and approval of the meeting minutes.

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01:59:47.810 --> 02:00:12.800
TELEPHONE_USER: So best practices for there to be, as it's been stated a couple times summary of the understanding of the focused questions and any other items that may have come up during that discussion. You know, if there's things that we need to follow up on, or you need to maybe provide us in order for us to. When I say the industry needs to provide us to. Maybe, you know, give them some feedback on a question that may not have been

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02:00:13.370 --> 02:00:22.759
TELEPHONE_USER: in the package when we're having the meeting. But any additional comments should be clearly identified in separate sections of the meeting minutes.

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02:00:23.260 --> 02:00:31.880
TELEPHONE_USER: The approval of the minutes. I will take note, because I like the comments that maybe making sure that everybody has

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02:00:31.920 --> 02:00:37.490
TELEPHONE_USER: seen those minutes prior to that being approved from the FDA side.

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02:00:37.530 --> 02:00:41.450
TELEPHONE_USER: and making sure that you know all parties who are, you know.

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02:00:42.140 --> 02:00:46.939
TELEPHONE_USER: part of that discussion, or that need to be part of that discussion, 'cause there may, they may be a

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02:00:47.210 --> 02:01:07.279
TELEPHONE_USER: signer of, said Ndr. BLA, that they should have seen those like. If we know it's an enemy. We want to make sure that the you know the office director has seen those and participated, and at least, you know, has had that. So I want to make sure I take a note of that to make sure we're doing that on our side as a better practice if it isn't being done all the time. Now.

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02:01:07.430 --> 02:01:29.229
TELEPHONE_USER: did you want to ask? Yeah. And I'll address the follow-up opportunities question. So there's been a lot of discussion about this today, and I suspect we'll probably have some more as we work through today. But I want to encourage sponsors to submit your follow-up questions in a timely manner.

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02:01:29.250 --> 02:01:46.550
TELEPHONE_USER: so that you can be considered in scope right? So they should be submitted within 20 days of your meeting minutes or WRO being issued. I also think that it's good to take a look at

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02:01:46.550 --> 02:01:59.329
TELEPHONE_USER: what questions you're asking. So clarification questions should truly be of a clarification nature, and not necessarily supplying us with any new information.

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02:01:59.330 --> 02:02:13.490
TELEPHONE_USER: So that's kind of, you know a broad statement. But just consider that if you're having to submit something, then it might not be considered a clarification question, because if we're seeing new information, then that

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02:02:13.510 --> 02:02:18.410
TELEPHONE_USER: wouldn't qualify and would be considered out of scope.

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02:02:19.269 --> 02:02:24.219
TELEPHONE_USER: Another thing I want to mention is that if you are

614
02:02:24.290 --> 02:02:28.430
TELEPHONE_USER: considering canceling the meeting, but have

615
02:02:28.530 --> 02:02:35.663
TELEPHONE_USER: just a few minor items, it might be best to actually have the meeting and square those away.

616
02:02:36.060 --> 02:03:01.349
TELEPHONE_USER: since if you do cancel the meeting, the follow-up opportunity isn't really applicable, it would just be easier, I think, on everyone if you had the meeting, and therefore could clear up any those few remaining issues that you may have. So again, I would encourage folks to schedule and have the meeting, especially if you've received the preliminary comments. And you think that it's

617
02:03:01.380 --> 02:03:09.929
TELEPHONE_USER: it's you know we've addressed everything, but if you have any kind of questions at all, it would be better just to have the meeting.

618
02:03:11.580 --> 02:03:18.849
TELEPHONE_USER: think that's it. Yeah. So we're about time for FDA side. With that

619
02:03:19.381 --> 02:03:26.210
TELEPHONE_USER: you all feel comfortable. Okay, and so now, industry, if you would like to. Respond to these questions.

620
02:03:26.900 --> 02:03:36.120
TELEPHONE_USER: thank you, and I think a lot of those remarks really resonate. I think, with our best practices that we discuss as well sort of within our industry groups.

621
02:03:36.340 --> 02:03:44.899
TELEPHONE_USER: And I think this idea of a recap has come up now several times, but I'll just say it again, and maybe add sort of a tactical spin to it.

622
02:03:45.200 --> 02:03:48.339
TELEPHONE_USER: You know we've talked about how it's helpful to make sure you're sort of

623
02:03:48.400 --> 02:04:08.109
TELEPHONE_USER: finding some sort of a verbal agreement, or repeating things that were discussed whether that's at the end of a section or at the end of the meeting, and I think tactically, maybe carve that into the agenda. Make sure that you're actually setting aside a few minutes that are sufficient to do that and make sure that you're avoiding misunderstandings, and maybe that can even help with the process of getting out the official written minutes faster.

624
02:04:09.770 --> 02:04:27.780
TELEPHONE_USER: These discussions. We think they can be done verbally. They can be done live on screen. We know that some review disciplines do use live meeting minutes, and we hear that they can definitely be helpful to accomplish this sort of objective as long as there is appropriate training in place for everybody involved.

625
02:04:27.780 --> 02:04:42.570

TELEPHONE_USER: I think what we want to avoid is a situation where producing the minutes and auditing them in real time sort of becomes the focus to the point that it's actually a distraction from the substantive discussion. So that's something to keep in mind. If we're thinking about doing this live on screen.

626
02:04:42.590 --> 02:04:50.930
TELEPHONE_USER: And then also, we suggest that it's a best practice for FDA to make sure that anything that is being requested of the sponsor is reflected in the meeting minutes.

627
02:04:51.020 --> 02:04:56.000
TELEPHONE_USER: I hear that this doesn't always necessarily happen consistency. So that's something to think about as well.

628
02:04:57.252 --> 02:05:02.229
TELEPHONE_USER: Moving to the second question, but still sort of related to meeting minutes.

629
02:05:02.240 --> 02:05:30.969
TELEPHONE_USER: We think it's a best practice for the sponsor to submit. Of course, timely requests to FDA, as was mentioned, for clarification when needed, and everybody hopefully is familiar with the PDUFA 7 commitment letter, if not, please go read it. Sponsors have 20 days to do this, following the receipt of the meeting minutes. But it's also important that FDA amend those minutes in response to a clarification request when that is appropriate. And when that is applicable, and hopefully, that's happening consistently and hopefully, that's a fair thing to ask for.

630
02:05:32.040 --> 02:05:53.419
TELEPHONE_USER: I think it's also worth thinking about. There might be some cases where a new question comes up after that twenty-day window. Or maybe there's a new question that comes up in between the cycle of a formal meeting request, and it would be really helpful to have. Maybe we can all think about what is the best way to address these questions without having to go through a more time-consuming formal mechanism.

631
02:05:53.420 --> 02:06:02.249
TELEPHONE_USER: We hear that some divisions, some rpms or reviewers, might be open to a quick phone call or some quick back and forth via email. But that is not always the case.

632
02:06:02.250 --> 02:06:18.109
TELEPHONE_USER: It can sort of vary by center. It can vary by division. And so maybe we can think about what are situations where it's appropriate to do this, and maybe there's a way to define some guardrails

around that and add a little bit of a process around it, and we can maybe do this in a way that helps reduce burden for both FDA and sponsors who are thinking through this.

633
02:06:18.290 --> 02:06:27.310
TELEPHONE_USER: and this could be helpful in a situation where FDA does provide a response to a follow-up request. But maybe the question wasn't really fully answered from the sponsor's perspective.

634
02:06:27.320 --> 02:06:45.269
TELEPHONE_USER: So I can give a CSL example. Speaking for myself, not for the company. We had a situation where we had a meeting request that was converted to a WRO. We had requested a live interaction. It was converted to a WRO, and that led to some additional questions because we couldn't really talk through them in real time.

635
02:06:45.300 --> 02:06:54.840
TELEPHONE_USER: And so we sent a clarification request, and FDA did respond within the time frame which was appreciated. But the response didn't really answer the critical question that was being asked.

636
02:06:54.870 --> 02:07:07.000
TELEPHONE_USER: And so now we have this challenge, where there's no longer a review clock, or there's no longer a timeline, and it's sort of hard for us to figure out how we should get more feedback and what that looks like and how long it will take, because there's really no recourse after that initial response comes.

637
02:07:07.140 --> 02:07:16.789
TELEPHONE_USER: and we understand that we're going to get a response most of the time. But when it's taken out of a formal review clock. It's sort of difficult for the sponsor, not knowing when it will happen.

638
02:07:16.920 --> 02:07:35.990
TELEPHONE_USER: and maybe even to put a finer point on it. I know there was the suggestion earlier to go to the above the RPM. But we don't really want to escalate up the review division if we don't have to. We would really prefer to work together and find a way to make the process work as intended with transparency. And so that's something that we can consider.

639
02:07:36.330 --> 02:08:04.020
TELEPHONE_USER: And then, finally, regarding the use of the follow-up opportunity itself, I think it came up earlier. Sponsors should not abuse that. Don't cancel your meeting, and then try to use the follow-up opportunity as a way to just sort of have your cake and eat it too, and again putting a sort of a tactical, hopefully constructive. Spin on that.

When you get those preliminary responses, take that back to your company, reach out to all your relevant teams, herd. The cats have the conversations, and make sure that everybody agrees that the responses were sufficient before you go out and cancel the meeting, and then change your mind

640
02:08:04.260 --> 02:08:06.239
TELEPHONE_USER: and happy to look to

641
02:08:06.770 --> 02:08:09.230
TELEPHONE_USER: other industry colleagues if I left anything out.

642
02:08:12.980 --> 02:08:14.029
TELEPHONE_USER: All right.

643
02:08:14.920 --> 02:08:38.549
TELEPHONE_USER: Well, good. Okay. Well, thank you for those responses to the questions. I'd like to open it up and looks like you might have. Yeah, I just, I wanted to follow up on the amending meeting minutes comments. We obviously do receive those requests, and we review them.

644
02:08:38.550 --> 02:08:54.979
TELEPHONE_USER: and in most cases, if the information in the meeting request is generally incorrect, we will reissue or not reissue but provide a updated response to those meeting minutes.

645
02:08:55.070 --> 02:08:58.470
TELEPHONE_USER: But editorial, or, you know.

646
02:08:58.690 --> 02:09:07.939
TELEPHONE_USER: very minor things we tend not to respond to and update. So I just. I wanted to provide that information.

647
02:09:07.960 --> 02:09:13.530
TELEPHONE_USER: And also, if you're if you're requesting clarification, that's not going to change the meeting minutes.

648
02:09:13.570 --> 02:09:15.800
TELEPHONE_USER: that's a separate communication to you.

649
02:09:15.930 --> 02:09:18.360
TELEPHONE_USER: So the meeting minutes will not be

650

02:09:18.390 --> 02:09:21.539
TELEPHONE_USER: changed on a request for clarification.

651
02:09:22.480 --> 02:09:29.279
TELEPHONE_USER: Just in general. That's how we've been handling. It's a separate communication to the sponsor

652
02:09:29.330 --> 02:09:45.009
TELEPHONE_USER: once we receive that because the clarification didn't occur during the meeting. Well, no, the clarification is usually something that's not about incorrectness. It's more of a. We need to make sure we're understood what you're saying. Clearly.

653
02:09:45.010 --> 02:09:59.659
TELEPHONE_USER: if the there's a kind of a 2 options here, you can request clarification for something that you just really didn't. What you wanna make sure that you're completely understanding versus you sending in something industry, sending in something that is

654
02:10:00.050 --> 02:10:08.630
TELEPHONE_USER: that do they feel is wrong reflected in the minutes. And again, typos, things of that nature we tend to not fix

655
02:10:09.320 --> 02:10:13.059
TELEPHONE_USER: doesn't change it substantively. Yes, got it. Thank you.

656
02:10:13.600 --> 02:10:27.499
TELEPHONE_USER: Yes, yeah. I also have one other comment. I think if you have received comments back from a follow-up opportunity where you're still unclear.

657
02:10:27.942 --> 02:10:31.320
TELEPHONE_USER: Again, I would encourage you to seek the

658
02:10:31.800 --> 02:10:58.729
TELEPHONE_USER: RPM. Aligned with that product and try to find a best way forward to get those questions answered. I know a lot of review divisions would ask you to submit that formally, and we could draft a response. It wouldn't necessarily result in an additional meeting needed. But again, have those discussions with the RPM and see what the best path forward is.

659
02:10:59.620 --> 02:11:12.600

TELEPHONE_USER: Okay? And yes, I'm just going to back up to sort of the best practices of taking meeting minutes, and this is something that I think is best sort of done up front to sort of

660
02:11:12.710 --> 02:11:24.899
TELEPHONE_USER: have both the sponsor and the review division align as to how we're going to summarize. I've sat through a couple of meetings. I think everybody has the best intentions. So we discussed 5 questions.

661
02:11:24.900 --> 02:11:49.070
TELEPHONE_USER: and everyone wanted to follow best practices. So we summarized after every question, and then we again summarized at the end. One can summarize too much. So I think it is very important in our division. We sort of lay out like we'd appreciate the summary at the end of every question, or if you're only discussing 2 questions, the summary at the end. But it was a bit much to

662
02:11:49.220 --> 02:12:02.619
TELEPHONE_USER: summarize each question for 5 min, and then summarize all 5 questions for yet another 10 min. So I think just to lay that out up front, I think, would make the meeting very much more streamlined and effective.

663
02:12:05.150 --> 02:12:32.259
TELEPHONE_USER: Yes, Alice, yeah, maybe just a slight change of discussion. So one of the things that industry really appreciates outside of PDUFA is when FDA gives us a heads up on something, and so I'll give an example. So if there's an impending clinical hold as an example, it's really helpful for us to just get a heads up and get some indication of what the issue is before anything formal is written by FDA,

664
02:12:32.260 --> 02:12:44.859
TELEPHONE_USER: really not fitting, perhaps, in this exact discussion, but just an example as to kind of these informal heads up or discussions is really helpful for us to figure out what we can do faster.

665
02:12:44.860 --> 02:13:02.289
TELEPHONE_USER: to kind of decrease the wasted time in our development programs. So I'm sure there's other examples here where industry is so thankful that FDA has kind of given us more information before something formal is written. It's really helpful for us.

666
02:13:07.576 --> 02:13:20.680
TELEPHONE_USER: Just a comment. About wasted time. You know, thinking about the clarification or clarifying question procedure. So you know you mentioned following up with the Rpm.

667
02:13:20.700 --> 02:13:34.292
TELEPHONE_USER: Some divisions are better than others on that. So you know, if you think about going through the formal process. I mean, theoretically speaking, you could turn into a 40 day, delay right? 20 days for each

668
02:13:35.620 --> 02:13:52.649
TELEPHONE_USER: Would it be possible or beneficial to think about what the bar may be, for something that needs to go through the formal process versus something that could sort of just be answered, sort of rather quickly, so that it there is more consistency across the divisions.

669
02:13:53.064 --> 02:13:56.250
TELEPHONE_USER: That that would help us out extremely, you know.

670
02:13:56.802 --> 02:13:58.069
TELEPHONE_USER: Because we could

671
02:13:58.760 --> 02:14:04.159
TELEPHONE_USER: better predict. You know, when we could get the answers we need, does that make sense?

672
02:14:05.000 --> 02:14:23.989
TELEPHONE_USER: Yeah, that absolutely makes sense. And you know, unfortunately, it's not one box for all questions that come in sometimes follow up clarifications could result in multiple disciplines that would need to address them so

673
02:14:23.990 --> 02:14:36.399
TELEPHONE_USER: that could contribute to also why you see variety across review divisions is it's not necessarily the review division. It's also your questions.

674
02:14:36.460 --> 02:15:02.929
TELEPHONE_USER: So it is a challenge. And I understand, and some things that come in, you know, we can quickly answer and turn them around other things, especially when there are multiple disciplines involved. We just can't turn them out and turn them around that quickly. So I think it's something that we can take back and definitely look into. But I understand that, you know, it's a challenge from your perspective.

675
02:15:03.620 --> 02:15:18.619
TELEPHONE_USER: And I'll just note that the guidance is still in draft format. And this public meeting is being used to help form some of these

areas that are new to us, these new meeting types and things of that nature. So I'm taking notes.

676
02:15:22.950 --> 02:15:24.940
TELEPHONE_USER: other comments.

677
02:15:25.010 --> 02:15:27.109
TELEPHONE_USER: questions, reflections.

678
02:15:32.590 --> 02:15:53.159
TELEPHONE_USER: you know. I'll just turn to the audience. Here we have. I've kind of asked a few questions that have come in virtually, but I also wanted to give the in-person audience members an opportunity. If you have any questions that you would like to ask our panelists.

679
02:15:53.654 --> 02:15:57.335
TELEPHONE_USER: In the 4 min that we have remaining in this section.

680
02:16:03.440 --> 02:16:12.479
TELEPHONE_USER: Hi, I'm Ann-Virginie Eggimann from Tessera Therapeutics. I do have a very quick question, probably more for the FDA.

681
02:16:12.500 --> 02:16:14.630
TELEPHONE_USER: It's more of a clarification.

682
02:16:15.209 --> 02:16:21.920
TELEPHONE_USER: We've talked about having virtual meetings or face to face meetings.

683
02:16:21.950 --> 02:16:51.219
TELEPHONE_USER: I wanted to confirm that there is the possibility to have a hybrid meeting where people are in person, and then maybe a couple of people from the sponsor who could not travel, for example, are allowed to be virtual. Yes, that's part of our next questions that we're going to be answering. So they're very timely. Thank you. Other questions from the audience, either in person or virtual.

684
02:16:54.600 --> 02:17:01.984
TELEPHONE_USER: Other comments, questions from our panelists. Lisa, I have one that's maybe a little bit nodding because it's off topic a bit. But

685
02:17:03.719 --> 02:17:05.200
TELEPHONE_USER: one thing

686
02:17:05.879 --> 02:17:21.000
TELEPHONE_USER: I don't know if you've guys thought about this. It's just well, kind of when are you done reviewing something? So, for example, if we're submitting protocols as part of an end to phase 2 meeting right, and their phase 3 protocols that they go into the IND. We'll get those 1st clinical hold

687
02:17:21.370 --> 02:17:26.860
TELEPHONE_USER: or not. Clinical. Hold questions. Come back, and then there's the other questions or other comments may come.

688
02:17:26.879 --> 02:17:55.090
TELEPHONE_USER: So then you get some comments, and then you think you're sort of done. And then comments might come quite a bit of time later, and maybe from a statistical reviewer, it might be from someone else commenting about something. So you're never quite sure when the review is actually complete on something that may be related to the initial meeting. But it may be related to something else. We submit down the way, is there any thoughts about? How do we know when you know we've sort of

689
02:17:55.209 --> 02:17:56.169
TELEPHONE_USER: are done

690
02:18:02.040 --> 02:18:28.410
TELEPHONE_USER: so I mean the way that I would look at it for an end of phase 2 meeting. You've submit. You've submitted a briefing book, and we've reviewed the information that's in that briefing book. We've provided you the responses, the preliminary responses. And then we have a meeting, and then there's meeting minutes. So I would consider the end of phase 2 meeting briefing background review at that point when the meeting minutes are issued. Unless

691
02:18:28.549 --> 02:18:39.049
TELEPHONE_USER: there's something pending in our meeting minutes that we identify the phase. 3 protocols that then come in. As a result of that end of phase 2 meeting.

692
02:18:39.080 --> 02:19:04.989
TELEPHONE_USER: they're usually identified as high priority protocols. And so our timeline to turn. There's a time. Obviously, as you know, a timeline to turn those around. And if we're going to have comments right, there is a timeline, right? I just want to make sure. So we have a timeline, and we try to communicate. If there's going to be comments on those protocols, because we don't want you to obviously start those studies without our

693
02:19:04.990 --> 02:19:28.889
TELEPHONE_USER: without our commentary in place. So I think if you're submitting phase 3 protocols, you know, we're looking at them when they're submitted to determine whether or not there's going to be comments on those, and we try to communicate right away that there are going to be comments, and then we follow our timelines, and we tell you when those comments would be coming to you. So at that point would consider the review of those comments

694
02:19:28.889 --> 02:19:53.110
TELEPHONE_USER: complete. But I do understand that it's sort of an ongoing process of, you know. And obviously the more things that you submit and sort of, you know, as we go that gets drawn out a little bit, but I will turn it over to the experts on the timelines for those high priority protocols. So we are just about at time. So if you can just respond briefly, I just wanted to say that I think we've recognized

695
02:19:53.110 --> 02:20:14.669
TELEPHONE_USER: this internally is a problem for some time now, and we're trying to work through some of that stuff internally. So hopefully, as we go on, you might see some improvement in how we're responding and making sure that sponsors know sponsors and applicants know when we've wrapped it up, and when we finish

696
02:20:14.670 --> 02:20:17.999
TELEPHONE_USER: I could say we would all appreciate that would be great.

697
02:20:18.940 --> 02:20:36.989
TELEPHONE_USER: all right. So thank you to you all. You've had a nice workout this morning with these topics and questions. We're going to break for lunch. And so we're going to take a forty-minute lunch break and we'll reconvene promptly at 1235.

698
02:20:37.230 --> 02:20:43.330
TELEPHONE_USER: So if you can be back here just before 1235. So we can start right on time. That would be great.

699
02:20:43.510 --> 02:20:44.959
TELEPHONE_USER: Thank you all so much.

700
02:21:23.130 --> 02:21:23.850
TELEPHONE_USER: Yeah.

701
02:21:30.190 --> 02:21:32.079
TELEPHONE_USER: everybody welcome back.

702
02:21:34.530 --> 02:21:41.463
TELEPHONE_USER: So thank you for coming back promptly, so we can get started. Appreciate it.

703
02:21:42.530 --> 02:22:00.880
TELEPHONE_USER: So I just wanted to mention a couple of housekeeping items before we get into our next panel discussion. One item is that you may have noticed this morning I was asking some questions that had come in and allowed both virtual and in-person folks to ask some questions

704
02:22:00.880 --> 02:22:13.729
TELEPHONE_USER: at this point. The volume of questions is so high that we won't be able to continue doing that this afternoon. We want to be fair, and how we are

705
02:22:13.950 --> 02:22:26.450
TELEPHONE_USER: providing opportunities for people to ask questions. And so but we will have questions and responses in the meeting summary that is generated after this meeting.

706
02:22:26.810 --> 02:22:53.629
TELEPHONE_USER: and that leads me to the second housekeeping item, and that is just as a reminder to folks in case you're interested. After this meeting, the slides and the recording of this meeting will be posted so that you all who are here, and other folks who weren't able to be here, either in person or virtually will have access to both the slides and the recording.

707
02:22:54.380 --> 02:23:06.539
TELEPHONE_USER: So with that, we'd like to get started into the next panel discussion. So if you all can advance the slides so that the folks can see the topic and questions on screen.

708
02:23:06.800 --> 02:23:22.830
TELEPHONE_USER: This is our 5th panel discussion topic, and that is in person and virtual face-to-face meetings. So for this morning sessions I asked all of the questions at once, and gave each group 5 min to respond.

709
02:23:22.830 --> 02:23:42.339
TELEPHONE_USER: because face-to-face and virtual are a bit different. I'm going to do this a little differently. I'm going to ask 1st about face-to-face and give you each 2 min to respond, and then ask about virtual, and give you each 2 min to respond, and then we'll open it up to general discussion.

710
02:23:43.260 --> 02:23:53.789
TELEPHONE_USER: So the 1st of the 2 questions is, what has been FDA's and industries' experience with face-to-face in-person meetings?

711
02:23:53.920 --> 02:23:59.290
TELEPHONE_USER: Are there best practices that could improve face-to-face in-person meetings.

712
02:23:59.520 --> 02:24:01.199
TELEPHONE_USER: So we'll start with that

713
02:24:01.240 --> 02:24:24.000
TELEPHONE_USER: and let me see, Pam, I think you're up. Yeah, I'll go ahead and take this question. I think that our experience with face-to-face meetings. Post-covid has initially started off as a little bit of a challenge. And for industry members who have participated in some of those earlier meetings

714
02:24:24.000 --> 02:24:37.160
TELEPHONE_USER: technology might not have caught up to us as quickly as we needed it to. But I think in most cases that has been resolved, and we've had some

715
02:24:37.250 --> 02:24:52.810
TELEPHONE_USER: overall. It's been a positive experience. We've had positive experiences with these face-to-face in-person meetings, and it's kind of returning to maybe what it was like before.

716
02:24:52.910 --> 02:24:55.510
TELEPHONE_USER: And and when I say we had tech

717
02:24:55.590 --> 02:25:19.050
TELEPHONE_USER: tech issues, it's because for the face to face meetings there is a hybrid component of those meetings. So there are, you know, currently, we try to limit the amount of individuals sitting in the room. So you do have a subset of individuals that are virtually calling in, and so

718
02:25:19.050 --> 02:25:26.249
TELEPHONE_USER: coordinating that virtual and in person interaction can sometimes be a little bit of a challenge. But

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02:25:26.250 --> 02:25:30.600

TELEPHONE_USER: I think we've worked our way through that, and it's worked pretty well

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02:25:31.217 --> 02:25:36.289
TELEPHONE_USER: and again, just going back to the limiting of

721
02:25:36.330 --> 02:25:39.679
TELEPHONE_USER: folks that are coming in for those in person meetings

722
02:25:39.960 --> 02:25:51.004
TELEPHONE_USER: I actually have found them to be. It's kind of nice not to have to. I don't know if any of you remember, drag chairs into the conference room from another conference room.

723
02:25:51.380 --> 02:26:03.750
TELEPHONE_USER: So, having the folks that really need to be there and talk about the topics is helpful, and not having to do that, and having everybody sit really close together.

724
02:26:03.860 --> 02:26:06.229
TELEPHONE_USER: I'll turn it over to the next person.

725
02:26:07.250 --> 02:26:10.880
TELEPHONE_USER: Yes, I'm gonna speak to best practices. I guess I don't have much time.

726
02:26:11.000 --> 02:26:21.210
TELEPHONE_USER: So just for the in-person piece right now. Yeah. So if you can just keep it brief. Yes, keep it brief. So I'll add what we haven't already discussed.

727
02:26:21.500 --> 02:26:51.000
TELEPHONE_USER: We already talked about limiting the people on campus. It's also important that you identify any foreign national attendees. These are people without a USA passport, because that clearance does have to go through HHS, which is beyond FDA. We need that time to get them cleared, and also to show up on time to navigate campus and security here and contacting your on-campus export. If issues arise, contact them immediately. So we can try to work through that.

728
02:26:52.060 --> 02:26:53.360
TELEPHONE_USER: Thank you.

729
02:26:53.879 --> 02:27:11.850

TELEPHONE_USER: I think that's me. I think overall. I mean, we obviously love every time we get to meet face to face with FDA, and we appreciate those opportunities we know they can be challenging, especially with the hybrid workforce that we probably both have these days.

730
02:27:13.890 --> 02:27:38.932
TELEPHONE_USER: but we do like the, you know, although we acknowledge the virtual meetings are important, which we'll talk about in a second. We do feel like there are times when face to face is necessary for us. So we try to be pretty critical about when we do ask for that. I mean, I think if the statistics said, only 18% of the time ish that we ask for face to face. So when we ask, there's usually a good reason for it.

731
02:27:39.789 --> 02:28:08.859
TELEPHONE_USER: For best practices. I mean, I was gonna talk about security. But it was the fastest that I've ever got into FDA today. You know, that's 1 thing that us as sponsors, you know, we have to think about. Obviously the number of people attending the meeting. And you know we like to travel to these meetings and bring our luggage in with us, and so sometimes that can back up security. So we, you know, we, as industry, you know, encourage people to think thoughtfully, to be thoughtful about what they're trying to get into the agency with.

732
02:28:09.113 --> 02:28:18.479
TELEPHONE_USER: Maybe leaving your luggage behind if you can. You know things like that, and just keeping in mind that security can take a while. So plan for that so that we can start the meetings on time.

733
02:28:20.500 --> 02:28:22.760
TELEPHONE_USER: Great, thank you.

734
02:28:23.600 --> 02:28:24.920
TELEPHONE_USER: All right.

735
02:28:25.040 --> 02:28:33.609
TELEPHONE_USER: So the second question, then, is, what has been FDA's and industry's experience with face-to-face virtual meetings?

736
02:28:33.750 --> 02:28:38.410
TELEPHONE_USER: Are there best practices that could improve face-to-face virtual meetings.

737
02:28:40.157 --> 02:28:48.739
TELEPHONE_USER: I'll start off with the experiences that FDA has had. Obviously the biggest one was we were able to continue doing business

738
02:28:49.199 --> 02:29:07.420
TELEPHONE_USER: during Covid, and that helped. Obviously there were some challenges in the beginning. We didn't know if we were coming back to work when we were coming back to work. Everybody's computers had to be upgraded to have you know the Zoom Gov and teams, and making sure everybody knew how to use them. There was

739
02:29:07.520 --> 02:29:21.649
TELEPHONE_USER: not a lot of time to train, so it did become a. It did become a lot easier. And it definitely was something that you know, we were grateful for at the time, because we didn't know how we were going to do business.

740
02:29:23.350 --> 02:29:39.939
TELEPHONE_USER: one of the things that we've we've noticed, you know I obviously work predominantly with Rpms and and with the clinical divisions, and on D, and one of the things that it allowed for us to do was when we were on those virtual platforms, you know, truly virtual.

741
02:29:40.380 --> 02:29:45.020
TELEPHONE_USER: We were able to have internal discussions while the meeting was occurring.

742
02:29:45.060 --> 02:29:57.819
TELEPHONE_USER: So while we're having meetings with industry. There may be a proposal or some other something that came up that industry wanted us to, you know, maybe opine on, and we would have our own internal chats

743
02:29:57.910 --> 02:30:06.449
TELEPHONE_USER: to be able to have those disciplines discuss that, and be able to give real time answers and not have to say.

744
02:30:07.050 --> 02:30:15.090
TELEPHONE_USER: we'll put that comment in the meeting as a post meeting. Comment. Meaning you're going to get it 30 days later, if it's not one of the live minutes.

745
02:30:15.571 --> 02:30:22.189
TELEPHONE_USER: So that gave us some real time. Benefits, you know, with having that ability

746
02:30:22.850 --> 02:30:49.380
TELEPHONE_USER: pre pandemic. I'm sure you all are very well aware we have not a lot of conference rooms for the amount of meetings that want to be held here, and all Rpms do is fight for conference rooms. So, and

those lead that that does also lead to extending our days. That we go, you know, beyond our timeframes that we're supposed to be meeting, and that's not a good

747
02:30:49.380 --> 02:31:08.360
TELEPHONE_USER: idea that has to say, well, we can't have your meeting until a month later, because I can't even find a conference room in all of these buildings that are here. So yeah, it's definitely something that you know has helped with alleviating some of that distress on as we've come back fully virtual or fully

748
02:31:08.540 --> 02:31:21.219
TELEPHONE_USER: in person, it has been able to help us, you know, alleviate some of those stressors that were that were helping that were not helping us meet goals and provide timely information to the sponsors.

749
02:31:21.770 --> 02:31:24.110
TELEPHONE_USER: I don't know if anybody wants to add anything.

750
02:31:24.740 --> 02:31:26.570
TELEPHONE_USER: I think Sonday has some.

751
02:31:28.330 --> 02:31:57.900
TELEPHONE_USER: Yes, just a few best practices. We talked about early, forego lengthy introductions on that virtual face-to-face. We tried to tag the phone numbers with names so that we know who you are. But you can just state your name before you start speaking. If that's helpful, alert your FDA host to any technical issues immediately recommend. You join 5 to 10 min before the meeting, if possible, to test your audio and your visual, so that we're not eating into the actual meeting time trying to fix

752
02:31:57.940 --> 02:32:26.070
TELEPHONE_USER: technical issues. And it's also very helpful if industry has somewhat experience with running these types of meetings on their side, monitoring that all of your participants are in able to join, able to hear. Because we really want to create that same face-to-face experience on the computer. And if someone can't hear, then they're at a disadvantage. And so, if you could help our rpms, make sure that everyone from your side is fully connected and able to hear. That would be great.

753
02:32:27.410 --> 02:32:29.059
TELEPHONE_USER: Great. Thank you.

754
02:32:29.240 --> 02:32:38.630

TELEPHONE_USER: And industry, yes, yeah. I mean, I think for the virtual component. I mean, I think the percentage of time that we request to face to face is

755
02:32:39.060 --> 02:32:54.739
TELEPHONE_USER: indicative of how successful the virtual meetings are. I mean, I think we generally would prefer these virtual meetings because our staff are not necessarily co-located anymore, as they used to be because of covid. Right? So I think once the technology caught up

756
02:32:55.060 --> 02:33:23.579
TELEPHONE_USER: with a with what we need, you know, for these face to face, virtual meetings that they're generally just as good for us, I mean, maybe even better, simply because we can have more staff potentially in the meetings. And maybe it's more or a little bit easier to get the right FDA stakeholders in these meetings as well. For scheduling purposes, or commute purposes, or things like that. So, generally speaking, we're pretty happy with them. And we definitely prefer

757
02:33:23.580 --> 02:33:52.640
TELEPHONE_USER: face to face virtual versus written response. Only, you know so I think the only thing for us is that you know from you know our stakeholders perspective has been, you know, that cameras are important in these face to face virtual meetings. I know that somebody mentioned earlier that it is policy to have the cameras on. That's not always our experience. So we do typically encourage all of our staff to have those cameras on. And so, being able to see the body language

758
02:33:52.640 --> 02:34:05.059
TELEPHONE_USER: and understand that people are paying attention, I mean, I'm not saying it's predominantly that way. It's just on occasion. There are situations where we don't have cameras on from the agency, and that could be very beneficial to us in these virtual meetings.

759
02:34:07.630 --> 02:34:10.588
TELEPHONE_USER: But, generally speaking, they're great.

760
02:34:11.880 --> 02:34:28.950
TELEPHONE_USER: great. Thank you. And on that we agree. Yes, it's always a happy thing. Right? So other comments, questions, reactions on either of these questions

761
02:34:28.960 --> 02:34:31.730
TELEPHONE_USER: face to face in person, face to face. Virtual?

762

02:34:34.970 --> 02:34:35.650
TELEPHONE_USER: Yes.

763
02:34:35.790 --> 02:34:40.505
TELEPHONE_USER: sure. So. Maybe. Just a brief comment, a sort of a logistical comment on the

764
02:34:40.840 --> 02:35:01.049
TELEPHONE_USER: I guess, for either an in person or a hybrid face-to-face meeting, so can totally appreciate the challenge of fighting for a conference room. I've also done that at White Oak and other places, and it's a difficult fight, but I'll say that there are maybe some edge cases that we can think about. So, for instance, you know we've had an example where we were. We had a hybrid meeting, but we were doing it with a partner.

765
02:35:01.090 --> 02:35:13.180
TELEPHONE_USER: so I think the limit was 6 attendees in person, and so it was sort of challenging to find the right people from 2 companies to sort of hit that or be below that threshold. So maybe it's helpful to have those conversations with FDA, and sort of be able to

766
02:35:13.250 --> 02:35:19.839
TELEPHONE_USER: ask about, you know, is there any flexibility on how many we can have in the room, and make sure that we are able to bring the people that we would like to bring.

767
02:35:23.149 --> 02:35:36.039
TELEPHONE_USER: There is flexibility now. Just so you're aware if the 6 and 6, I think, was during our 1st phases. But now that we're fully virtual as long as we can fit them in the conference people in the conference room.

768
02:35:36.170 --> 02:35:39.600
TELEPHONE_USER: and the number is right around

769
02:35:39.840 --> 02:35:42.160
TELEPHONE_USER: 25, I want to say 26.

770
02:35:42.809 --> 02:35:52.069
TELEPHONE_USER: So that that's probably the limit. They're not. I don't. I don't know if anybody's been to a face to face meeting recently in any of our newly

771
02:35:52.100 --> 02:36:06.369

TELEPHONE_USER: renovated conference rooms. But if you remember, there used to be chairs against the back wall of the table. Those are gone. They've taken those out. So that's why our numbers have gone down with the amount of people that can be in the room, even fully open.

772
02:36:11.140 --> 02:36:18.738
TELEPHONE_USER: And I just wanted to note that we do that so that the online participants can hear. Well, if you sit in the back, no one can hear

773
02:36:22.620 --> 02:36:23.430
TELEPHONE_USER: alright

774
02:36:24.040 --> 02:36:26.050
TELEPHONE_USER: other comments.

775
02:36:26.460 --> 02:36:28.460
TELEPHONE_USER: questions, reactions.

776
02:36:28.800 --> 02:36:42.180
TELEPHONE_USER: Yeah, I just wanted to follow up with the comment that we had earlier with regards to the question, if we could have a hybrid component, did you get your question answered.

777
02:36:42.240 --> 02:36:43.919
TELEPHONE_USER: okay, thank you.

778
02:36:45.720 --> 02:36:46.680
TELEPHONE_USER: All right.

779
02:36:49.470 --> 02:36:50.530
TELEPHONE_USER: Okay.

780
02:36:51.500 --> 02:36:53.730
TELEPHONE_USER: Other comments, questions.

781
02:36:55.960 --> 02:36:57.270
TELEPHONE_USER: reactions.

782
02:37:01.240 --> 02:37:03.520
TELEPHONE_USER: all of our problems have been solved.

783

02:37:06.010 --> 02:37:07.270
TELEPHONE_USER: Okay?

784
02:37:07.700 --> 02:37:16.080
TELEPHONE_USER: All right. Well, if there's nothing else on this topic, we can actually move to the next topic.

785
02:37:16.300 --> 02:37:20.849
TELEPHONE_USER: And so that is interact and type d meetings.

786
02:37:22.020 --> 02:37:35.819
TELEPHONE_USER: And so here we'll go back to the format that we were using before. I'll give you each 5 min to answer both of the questions. So the 1st question is, are there potential best practices for interact

787
02:37:35.860 --> 02:37:37.759
TELEPHONE_USER: that could improve their use?

788
02:37:38.700 --> 02:37:45.660
TELEPHONE_USER: History experience different approaches for track meetings, requests between CDER and CBER?

789
02:37:46.520 --> 02:37:52.369
TELEPHONE_USER: Then the second question is, are there potential best practices for type d meetings

790
02:37:52.410 --> 02:37:54.160
TELEPHONE_USER: that could improve their use?

791
02:37:54.480 --> 02:38:02.450
TELEPHONE_USER: Does industry have any case? Studies where type d meetings successfully supported innovative approaches in drug development.

792
02:38:03.210 --> 02:38:11.619
TELEPHONE_USER: And so we will start out again with 5 min for FDA and Romani. I think you're going to lead us off.

793
02:38:13.600 --> 02:38:32.529
TELEPHONE_USER: I'll start with interact. We discussed this before. When you are requesting, make sure the criteria for interact meeting request is met not too early, but at the same time, you know not late enough that it qualifies for pre-ind.

794
02:38:32.600 --> 02:38:43.240
TELEPHONE_USER: Another thing that we can suggest is to make the meeting descriptive. This came up before, too, you know. Try to make it as descriptive as possible.

795
02:38:43.250 --> 02:38:57.749
TELEPHONE_USER: Try to make it multidisciplinary, although we say Cmc and pharmtalx non-clinical mostly, for interact. Also think about

796
02:38:57.750 --> 02:39:17.349
TELEPHONE_USER: clinical, if it's a product and indication for rare disease pace, you know, this would actually be a good time to bring that up also, so that you know anything that can be further discussed and teased out in Priya, indeed will be, you know, helpful to them.

797
02:39:18.017 --> 02:39:24.689
TELEPHONE_USER: Sponsor and in Otp, specifically, if you are planning

798
02:39:24.690 --> 02:39:51.640
TELEPHONE_USER: the same product for multiple indications, and you know, think about a platform technology meeting. And then, when in doubt, you know, reach out to the Rpm. On the file or the RPM. For the group. The RPM is someone who can guide you through what to do next before requesting the meeting if there are any questions.

799
02:39:57.040 --> 02:39:58.979
TELEPHONE_USER: Yes, yes, please go ahead.

800
02:39:59.780 --> 02:40:25.200
TELEPHONE_USER: So I'm going to go ahead and take the best practices for type D meetings. I think. You know, this is a new meeting type. So we're all sort of trying to learn how to use it and what works best and sort of trying to keep sort of to the letter of the guidance. I think one of the most important things is to ensure that the scope of the meeting is appropriate for a type d meeting

801
02:40:25.270 --> 02:40:46.859
TELEPHONE_USER: both. I think that I think we all sort of get right. The number of disciplines and the number of questions. I don't think that anybody has a big problem. With that I think one of the things that sometimes, you know, can become somewhat of a judgment call is the complexity of the package. And so to really ensure that there's a narrow focus to the questions.

802
02:40:46.860 --> 02:40:57.820

TELEPHONE_USER: and that they're, you know they're not. It's not a highly, because a highly complex single issue will still require, maybe multiple discipline some more time to discuss.

803
02:40:57.820 --> 02:41:22.059
TELEPHONE_USER: And so that would be better requested as a type C meeting, for example, rather than a type d meeting. So I think if there's confusion or questions always reach out to the clinical division to see why is it not appropriate for a type d meeting? So we can sort of all learn from these. But that's the most common scenario I'm seeing is where we sort of have the right number of disciplines, the right number of questions.

804
02:41:22.060 --> 02:41:28.760
TELEPHONE_USER: the complexity sort of doesn't fit into sort of the spirit of the guidance.

805
02:41:30.980 --> 02:41:31.860
TELEPHONE_USER: Okay.

806
02:41:32.980 --> 02:41:36.159
TELEPHONE_USER: anything else from FDA on your end?

807
02:41:37.900 --> 02:41:40.220
TELEPHONE_USER: Just move to industry.

808
02:41:41.700 --> 02:42:03.690
TELEPHONE_USER: sure. So, of course, as always, the brief disclaimer that these views are my own, and also informed by discussions that we're having at industry associations as well as experiences at the CSL, but not representing CSL, so I think starting with interact. We can certainly empathize with the idea that we're still learning. We're really trying to figure out how to best leverage these meetings and realize their potential.

809
02:42:03.720 --> 02:42:32.739
TELEPHONE_USER: I think, looking at some of the preliminary data that we saw in the FDA fiscal year 23 PDUFA performance report, we sort of have the sense that sponsors maybe are not requesting quite as many interact meetings as we would expect. And I'm sure that part of this is just due to the fact that by definition interact meetings happen at a very specific phase in development. But I think there's also this sense that industry. Other sponsors are really not quite sure, when an interact meeting is appropriate in practice.

810
02:42:32.760 --> 02:42:44.930

TELEPHONE_USER: we hear about some general uncertainty in terms of what types of questions are appropriate, what types of topics are appropriate and sort of what the really ideal, what the appropriate meeting timing would be for an interact.

811
02:42:45.030 --> 02:42:55.960
TELEPHONE_USER: And so I think it would be helpful, probably for the broader industry to have some more information, whether it's through guidance, whether it's through training or some other mechanism that addresses some of these questions that keep cropping up.

812
02:42:56.170 --> 02:43:03.399
TELEPHONE_USER: And so, I think, sort of thinking about differences between CBER and CDER, just like I mentioned. It's sort of hard to

813
02:43:03.400 --> 02:43:26.750
TELEPHONE_USER: answer what differences in approaches or best practices would be just because we are still learning, and we just don't have that much experience yet. But it's worth stating. I think, that the idea of consistency between CDER and CBER, when appropriate, given differences in products is really important, and those criteria that are being applied to decide whether or not, these meetings are being granted the consistency there is really a top priority for sponsors.

814
02:43:27.260 --> 02:43:47.429
TELEPHONE_USER: We do know that FDA has stated, I think, that CDER has less experience with interact than CBER so far, which sort of matches the industry perception as well. So it's hard to say whether there's a major trend of divergence just yet. But we should make sure that we're thinking about being collaborative and sharing the lessons learned along the way to make sure consistency is there from the start, and that we're not diverging.

815
02:43:47.510 --> 02:43:55.140
TELEPHONE_USER: And so, if idea has ideas on differences in an ideal meeting request between CDER and CBER products, I think that would be helpful to have in the guidance or some other form.

816
02:43:57.530 --> 02:44:18.799
TELEPHONE_USER: So, looking again at the 2023 report that I mentioned, we can see that so far, I think about, or less than half of requests have been accepted in some form. So whether it's a meeting or a WRO, I think 57% of requests were denied in fiscal year 23, and of those that were granted, I think we saw today that almost a 3rd of them were converted to a WRO.

817
02:44:18.860 --> 02:44:34.830

TELEPHONE_USER: And so I think we also saw that maybe there's been some improvement. If you add those extra 2 quarters that we saw today in terms of what's being granted. But it would be interesting to see how much conversion to WRO is still happening, even though more requests are potentially getting granted overall.

818
02:44:36.140 --> 02:45:02.919
TELEPHONE_USER: I think, looking at some of the reasons for why interact meetings are being denied. It just underscores this idea that we're still learning. We're not quite there in terms of our collective understanding and transparency. And so I think it's helpful to understand, you know, if the questions being posed by the sponsor would be more appropriate for a pre-ind meeting, maybe having some more guidance about examples. Why, that's happening would be helpful for sponsors, sort of understanding how FDA is making decisions about ideal timing and what factors go into that.

819
02:45:04.560 --> 02:45:26.589
TELEPHONE_USER: if the meeting package is missing, I think we can all agree. That's probably the sponsor's fault. But if the package is incomplete, or if the data is inadequate, is that because the sponsor didn't make a mistake, or is it because certain data aren't available yet because of where we are in development? Or is it because there's some other standard that FDA is maybe considering, or parts of FDA are considering, that the sponsors might not be aware of when FDA is making these decisions.

820
02:45:26.730 --> 02:45:54.780
TELEPHONE_USER: and I think another reason that was cited is situations where a sponsor is requesting an interact for multiple indications. And so just to make the point, I know the platform designation came up earlier, but it would be helpful to think about what is the ideal mechanism to discuss these situations where maybe a sponsor is filing multiple Ind's with related issues that have the same questions. What is the most efficient way for a sponsor to discuss that with FDA? If not, interacts? And

821
02:45:54.870 --> 02:45:56.750
TELEPHONE_USER: if you don't get a Ptd

822
02:45:58.070 --> 02:46:10.500
TELEPHONE_USER: And the final point I'll make about interact is if the request is being denied. It's really important to industry that FDA is explaining the rationale to the sponsor and providing sort of next steps and a path forward to make sure that we can find the device that we're looking for.

823
02:46:11.270 --> 02:46:36.690

TELEPHONE_USER: Okay? So switching to Type DI think there have been a lot of positive experiences so far. We know that, especially compared to interact, a lot of type D meeting requests are being accepted, but I think still about 17% of them are being converted to another type. So it would be helpful to understand if there are any trends behind those decisions to convert, and maybe, is there a need for more specificity and guidance, or otherwise, to make sure FDA is getting on track requests.

824
02:46:36.790 --> 02:46:59.780
TELEPHONE_USER: So I can give an example. CSL Had a case where we requested a type d. Meeting. FDA converted it to a type C, but they provided the feedback that we were not quite at the appropriate stage in terms of our top line results in summary. So the feedback made sense and we appreciate it. They worked with us to find sort of a more appropriate mechanism, and we learned from that we didn't make the mistake again. So that sort of feedback is really helpful.

825
02:47:01.260 --> 02:47:26.790
TELEPHONE_USER: I think we also saw today that just over half of type D requests are being converted to WRO, and sometimes when we request a WRO. Specifically, we feel that it would be sufficient. But for all meeting types, not just type D, we find that when we request a face-to-face. But get a written response. We're almost always left with more questions and have to pursue some type of follow-up. So I think in these cases the best practice would be to grant a live interaction when it's requested by the sponsor and allow for that dialogue to happen.

826
02:47:30.110 --> 02:47:58.390
TELEPHONE_USER: you know. And I can. Yeah, probably running out of time. Yeah, I was gonna say, but we can, you know, go into I there's a lot to unpack on what all of you have contributed thus far. So if you have other comments, you can probably weave them in to the discussion. So would anyone like to start us off on kind of comments and

827
02:47:58.390 --> 02:48:02.459
TELEPHONE_USER: reflections on some of what? You all brought up

828
02:48:02.930 --> 02:48:04.280
TELEPHONE_USER: for? These questions?

829
02:48:05.740 --> 02:48:12.790
TELEPHONE_USER: Maybe just a question to the update. Really around the actually, it's really that last question or the last question, the

830
02:48:13.090 --> 02:48:33.560
TELEPHONE_USER: I guess in our maybe Jansen experience, the type D's have become more of a more of a simple single topic kind of question. So it's

interesting to remember that I think the type D's were originally envisioned to help support innovative approaches. But I'm not sure, really. That's what they're morphing into. They're more of a

831
02:48:33.800 --> 02:48:59.539
TELEPHONE_USER: get clarity. Try to drive to resolution on a less complex topic. Just to think about some of the commentary you provided is that your experience as well? And I can only speak towards my division, and I'll look to everyone else who sort of has a broader view. But yes, I do think that that's sort of what they've morphed into is sort of these very specific, because I do think also, I mean, it's almost.

832
02:48:59.820 --> 02:49:21.000
TELEPHONE_USER: There's a little bit of a dichotomy when you say it has to be simple, narrow, focused, and like sort of easily answerable. And then, like, you have, like a complex question about innovative design. So I think there is a little bit of push and pull there, and I know we're still learning from that. But we haven't seen a lot of the type D meetings utilized for that purpose

833
02:49:21.070 --> 02:49:22.960
TELEPHONE_USER: specifically in my division.

834
02:49:28.030 --> 02:49:33.479
TELEPHONE_USER: others from FDA. Do you have? Similar experiences or different observations?

835
02:49:36.690 --> 02:50:00.190
TELEPHONE_USER: Yeah, I don't know that we have enough experience with them. I know that we're trying to utilize some of the data that we have received, like when they've gotten denied, and things of that nature to give some examples, and the guidance, and utilize some of the information. We're getting here to try to make sure it's very clear what the intention was for them, and making sure we're not changing that focus.

836
02:50:00.760 --> 02:50:08.439
TELEPHONE_USER: And I can't speak to all the divisions, unfortunately. But, I would assume that they're not utilizing them all the exactly the same

837
02:50:08.900 --> 02:50:15.750
TELEPHONE_USER: like, we don't all the time the business have their uniqueness. So

838
02:50:18.977 --> 02:50:40.120

TELEPHONE_USER: yeah, you guys showed a slide. Is there another icon? No for the interact and why those were denied. It might actually be helpful for us to see something similar for a type D to see, like some of the reasons that those are denied or or changed to a different meeting format. Just so we have a better idea of what the criteria are that you guys are using

839
02:50:43.900 --> 02:50:44.455
TELEPHONE_USER: right?

840
02:50:45.090 --> 02:50:46.330
TELEPHONE_USER: Allison.

841
02:50:46.650 --> 02:50:59.200
TELEPHONE_USER: yeah, a couple of things. So 1st of all, in regards to case studies, we had very similar examples as CSL described in that initially, you know, we tried to request a few type DS, and we learned

842
02:50:59.200 --> 02:51:27.619
TELEPHONE_USER: with the feedback. So what to request and what not to request is a type D, and so I think there's perhaps a theme which is, you know, if we can communicate well together, and just give each other rationales and try to be descriptive. Then, hopefully, we can get better at many of these things, and we don't need more best practices meetings, because we're pretty good at it, which then leads to my second item, which is my understanding, is that

843
02:51:27.630 --> 02:51:36.099
TELEPHONE_USER: perhaps from this meeting or thereafter, there will be an update on best practices for meeting management.

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02:51:36.240 --> 02:51:57.979
TELEPHONE_USER: I think that will be very helpful for industry, and it would be great if you could give some of the examples that we were describing. You know. What have you seen from industry that doesn't work as an example, and try to provide some of that description as you do. I know in other things in Q&A's and that type of thing so that we can take a look at that. And you know, if it's written down, we usually don't do it.

845
02:52:06.170 --> 02:52:09.200
TELEPHONE_USER: Other comments. Questions.

846
02:52:13.450 --> 02:52:21.660
TELEPHONE_USER: Alex. It looked like you were. You had some other thoughts at the end of your comments. Did you want to say something else

847
02:52:22.170 --> 02:52:42.830
TELEPHONE_USER: not to put you on the spot. I mean, I can talk as long as people want to listen about this. I mean, maybe just adding to the list of anecdotes. So we sort of had our learning experience. That it sounds like is sort of a common theme. We've also had successful type D experiences. We've used it to get feedback on Cmc topics. We've used it for non-cmc topics. So just to sort of underscore the fact that

848
02:52:42.830 --> 02:53:01.340
TELEPHONE_USER: sort of the appropriate scope is broad. It's just this question about what is the appropriate level of complexity, I think, is the theme, and that's where I think the guidance is helpful is understanding. There's not a 1. Size fits all for a question like, what amount of complexity is okay. But I think more examples, more guidance will help us get closer to that line.

849
02:53:06.900 --> 02:53:07.680
TELEPHONE_USER: Okay.

850
02:53:10.240 --> 02:53:13.449
TELEPHONE_USER: other comments, questions for each other.

851
02:53:13.950 --> 02:53:20.349
TELEPHONE_USER: No, maybe it's just a just a thing, the obvious. But you know, because of the timeline for the type days is

852
02:53:20.440 --> 02:53:24.720
TELEPHONE_USER: quicker. It is much appreciated by interested that we have at least one mechanism where we can get

853
02:53:24.870 --> 02:53:41.559
TELEPHONE_USER: simpler question, but a critical one answered quicker. So we appreciate you playing along. And you know, I think there's probably we're seeing reason quite a bit, and I think it is helpful for us. So we appreciate those

854
02:53:47.670 --> 02:53:48.530
TELEPHONE_USER: right.

855
02:53:50.260 --> 02:53:51.460
TELEPHONE_USER: Anything else

856
02:53:53.260 --> 02:53:54.840

TELEPHONE_USER: comments, questions.

857
02:53:57.660 --> 02:53:59.160
TELEPHONE_USER: anything to unpack.

858
02:54:05.440 --> 02:54:06.670
TELEPHONE_USER: All right.

859
02:54:07.010 --> 02:54:12.310
TELEPHONE_USER: Well, thank you. Panelists for

860
02:54:13.350 --> 02:54:14.290
TELEPHONE_USER: your

861
02:54:15.590 --> 02:54:22.590
TELEPHONE_USER: your time and patience and thoughtfulness in responding to all of these questions

862
02:54:22.710 --> 02:54:36.939
TELEPHONE_USER: and your endurance, and being up here on the spot for hours on end. So thank you to all of you for your participation in these panel discussions.

863
02:54:37.823 --> 02:54:40.716
TELEPHONE_USER: You are welcome to.

864
02:54:41.908 --> 02:54:47.890
TELEPHONE_USER: Stay up here if you wish, or you can. Come back into the audience.

865
02:54:47.900 --> 02:54:53.000
TELEPHONE_USER: We're going to go into the public comment period shortly.

866
02:54:53.040 --> 02:55:01.210
TELEPHONE_USER: So you're welcome to stay up here and listen, if you would like to the public comments.

867
02:55:02.201 --> 02:55:08.100
TELEPHONE_USER: But if you prefer, you can go into the audience, that's also acceptable.

868
02:55:08.480 --> 02:55:10.520

TELEPHONE_USER: Okay, I'm going to

869
02:55:11.600 --> 02:55:21.879
TELEPHONE_USER: relocate over to the podium so that I can see the audience now and invite public comments shortly.

870
02:55:36.060 --> 02:55:38.700
TELEPHONE_USER: All right, I am back.

871
02:55:39.130 --> 02:55:39.955
TELEPHONE_USER: So

872
02:55:40.990 --> 02:55:50.499
TELEPHONE_USER: So once again I want to thank also. Paul, earlier for the informative presentation, as well as all of our panelists.

873
02:55:51.052 --> 02:55:54.670
TELEPHONE_USER: For their time and contributions to this workshop.

874
02:55:54.890 --> 02:56:20.930
TELEPHONE_USER: In this workshop, on best practices and meeting management, FDA presented insights into recent trends in PDUFA meeting activities. I think that was really useful for a lot of folks to see kind of what those patterns are, and to kind of keep that in mind as we're thinking about best meeting management practices.

875
02:56:22.400 --> 02:56:30.350
TELEPHONE_USER: both FDA and industry provided a lot of perspectives on several topics related to PDUFA meetings.

876
02:56:30.510 --> 02:56:42.089
TELEPHONE_USER: and you know, as I reflect on the conversations that we've all had, you know, I think about there being a lot of

877
02:56:42.290 --> 02:56:43.396
TELEPHONE_USER: kind of

878
02:56:44.360 --> 02:56:55.600
TELEPHONE_USER: a lot of energy and a lot of kind of commitment to trying to work with each other as effectively as possible.

879
02:56:55.610 --> 02:57:07.320

TELEPHONE_USER: And so I hear from industry very understandably that it is helpful to get as clear, complete

880
02:57:07.430 --> 02:57:25.910
TELEPHONE_USER: kind of information, advice, responses as possible, and as promptly and as early as possible, so that you are able to make decisions and plan with your development programs.

881
02:57:25.970 --> 02:57:39.240
TELEPHONE_USER: And so you know, that is, you know, a very understandable kind of, you know, frame of reference. And you know, and on FDA side.

882
02:57:39.440 --> 02:57:48.990
TELEPHONE_USER: you know, you all are very kind of committed to working with industry and trying to provide information and guidance.

883
02:57:49.598 --> 02:57:59.969
TELEPHONE_USER: You know to be as helpful and practical as you can. And you also, it's helpful for you to have

884
02:57:59.980 --> 02:58:17.629
TELEPHONE_USER: kind of clearly articulated questions, complete kind of information, packages and questions that are appropriate to the stage of development, so that you can answer those questions and provide advice

885
02:58:17.630 --> 02:58:37.820
TELEPHONE_USER: effectively. And there's always going to be kind of that balancing act right of kind of sometimes wanting broader or more kind of answers earlier versus having enough to be able to provide advice and answers in a way that

886
02:58:38.560 --> 02:58:42.160
TELEPHONE_USER: that is going to hold true.

887
02:58:42.350 --> 02:59:09.659
TELEPHONE_USER: because if FDA tries to provide too broad or answers too early before they have sufficient information. Then there's a higher risk of that guidance, or some of the suggestions changing. And so there's always that kind of dance that happens between industry and FDA, wanting to engage effectively and impactfully with each other.

888
02:59:09.730 --> 02:59:33.589
TELEPHONE_USER: and how to do that as best as possible. And what I see here is a lot of really kind of genuine interest and commitment to try to make that happen as effectively as possible. So I really applaud all of

you for your efforts to really understand. Communicate your own kind of frame of reference while understanding

889
02:59:33.850 --> 02:59:36.889
TELEPHONE_USER: kind of the position of the other parties.

890
02:59:36.980 --> 02:59:53.600
TELEPHONE_USER: So thank you really, for I think, being very thoughtful and respectful in trying to communicate your needs and goals, while also understanding the bigger context.

891
02:59:56.030 --> 03:00:12.340
TELEPHONE_USER: so, by engaging in these discussions, I think both FDA and industry hope to gain a greater understanding of current meeting management, best practices and areas for improvement. And I think we have a lot of

892
03:00:12.370 --> 03:00:16.269
TELEPHONE_USER: kind of food for thought coming out of this meeting.

893
03:00:18.450 --> 03:00:44.620
TELEPHONE_USER: so another important factor that can inform improvements in PDUFA meeting management processes is feedback from interested parties in the form of public comments. So I'm going to put in another plug for submitting comments in writing to the best practices for meeting management, public workshop docket

894
03:00:44.830 --> 03:00:53.520
TELEPHONE_USER: on regulations.gov, and you can submit those comments until August 20, second, 2024.

895
03:00:54.580 --> 03:01:10.830
TELEPHONE_USER: And so now we do have some folks who have signed up for providing public comments during this session. So we'd like to open that session now.

896
03:01:11.080 --> 03:01:23.940
TELEPHONE_USER: And so at this point I'd like to welcome you all to the public comment portion of this workshop on best practices for meeting management.

897
03:01:25.100 --> 03:01:43.690
TELEPHONE_USER: So there was actually quite a large volume of requests to present comments and limited time available. And so we selected members

of the public to offer comments on a first-come, first-served basis, and then went through a process of confirming with folks

898
03:01:43.690 --> 03:02:02.499
TELEPHONE_USER: whether or not they would actually present comments, and in so doing there were 3 individuals who confirmed that they would like to present public comments during this session. So we will have those 3 today.

899
03:02:02.850 --> 03:02:27.819
TELEPHONE_USER: So I will introduce the public commenters in order. Each person will have 2 min to share comments, and may show an accompanying slide, because only 3 people actually confirmed. We do have a little bit of wiggle room on that time frame. I'm not going to be strict in limiting people to 2 min. So if it's

900
03:02:28.070 --> 03:02:30.170
TELEPHONE_USER: 2, 3, 4

901
03:02:30.340 --> 03:02:33.959
TELEPHONE_USER: up to 5 min, you know, I think we're going to be fine.

902
03:02:35.140 --> 03:02:41.679
TELEPHONE_USER: Just please keep in mind that we won't be addressing the comments that we hear during this session.

903
03:02:41.950 --> 03:02:46.299
TELEPHONE_USER: But all of the comments are being transcribed as part of the public record.

904
03:02:46.970 --> 03:02:49.839
TELEPHONE_USER: We'd like this to be a transparent process.

905
03:02:49.990 --> 03:02:55.049
TELEPHONE_USER: So we encourage you to note any financial interests that may be relevant to your comment.

906
03:02:55.660 --> 03:03:00.190
TELEPHONE_USER: If you do not have any such interest. You may wish to state that for the record.

907
03:03:00.430 --> 03:03:05.800
TELEPHONE_USER: and if you prefer not to provide this information, you can still provide your comments.

908
03:03:06.790 --> 03:03:18.370
TELEPHONE_USER: So the 1st presenter is Anne Virginie Eggimann from Tessera Therapeutics, Inc. And Anne, you may begin.

909
03:03:26.390 --> 03:03:37.689
TELEPHONE_USER: Thank you for the opportunity to speak. Today I'm Anne Virginie Eggimann. I'm chief regulatory officer at Tessera Therapeutics, a genome editing Biotechnology company.

910
03:03:37.990 --> 03:04:02.979
TELEPHONE_USER: I do have one slide. Thank you. As an alternate member of the PDUFA 7 team. I'm pleased that the FDA organized this workshop today to share their progress and to receive feedback on how to further optimize the management of meetings with industry which, as highlighted this morning, are crucial for sponsors to reduce regulatory uncertainty, particularly for innovative products.

911
03:04:03.260 --> 03:04:09.239
TELEPHONE_USER: We have 8 recommendations ranked by estimated impact from highest to lowest.

912
03:04:09.770 --> 03:04:17.660
TELEPHONE_USER: These recommendations are based on the ultimate goal to increase drug development efficiency and are mostly focused on operational aspects.

913
03:04:17.900 --> 03:04:30.889
TELEPHONE_USER: However, they do not negate the importance for the agency to provide consistent feedback from sponsor to sponsor, reviewer to reviewer, and throughout the development of products, unless there is a clear policy change.

914
03:04:32.160 --> 03:04:33.910
TELEPHONE_USER: So here I go.

915
03:04:35.160 --> 03:04:53.429
TELEPHONE_USER: number one. When meetings are granted. It would be ideal if the agency could shorten the time from receipt of meeting requests to the actual meeting, and from the time from the meeting to receipt of minutes, especially when FDA responses are rate limiting for development

916
03:04:54.530 --> 03:05:05.399

TELEPHONE_USER: number 2, we recommend the agency adhere to time, allocated for sponsors to review FDA preliminary responses prior to meetings as indicated on this slide.

917
03:05:05.520 --> 03:05:24.820
TELEPHONE_USER: it is challenging for sponsors to prepare well for a meeting when FDA, pre-meeting feedback is received late in the evening before the meeting, for example, also, if pre-meeting feedback is received on time, this may increase the likelihood of having a clear discussion on an alternative scenario. When applicable.

918
03:05:26.810 --> 03:05:43.619
TELEPHONE_USER: Number 3, we strongly recommend maintaining option to request either fully virtual hybrid or all in-person face-to-face meetings as discussed today. We all think it's very helpful to be able to have these live discussions written. Responses

919
03:05:43.750 --> 03:05:49.809
TELEPHONE_USER: only should be avoided when sponsors request a face-to-face meeting whenever feasible

920
03:05:52.020 --> 03:06:13.709
TELEPHONE_USER: number 4, the agency should establish a next-generation cloud-based electronic submission gateway with the capability to track applications including the meeting request process. So a sponsor could know exactly where it is in the different steps without necessarily having to bother the RPM.

921
03:06:14.080 --> 03:06:30.940
TELEPHONE_USER: This should also help to easily document correspondence between sponsors and the regulatory project manager and the reviewers, including informal correspondence and informal phone calls. We believe this will make the development more efficient.

922
03:06:33.650 --> 03:06:42.759
TELEPHONE_USER: The agent number 5, the agency should allow the opportunity to request Cmc-focused meetings during development. In addition to existing PDUFA meeting Types

923
03:06:44.430 --> 03:06:45.669
TELEPHONE_USER: Number 6,

924
03:06:46.210 --> 03:06:55.329
TELEPHONE_USER: FDA should create a simple online form for requesting meetings. This would streamline the process and hopefully facilitate meeting date scheduling.

925
03:06:55.920 --> 03:07:09.020
TELEPHONE_USER: Some of my colleagues have referred to this as using something like when you reserve restaurants, but I don't know if we'll ever get to that, but just wanted to add this visual for everyone.

926
03:07:10.380 --> 03:07:24.290
TELEPHONE_USER: Number 7. FDA should consider actively supporting communication plans throughout development for breakthrough therapy and armat-designated products ideally with senior staff involvement, at least for end of phase meetings.

927
03:07:26.600 --> 03:07:38.960
TELEPHONE_USER: Lastly, number 8 FDA. Should consider setting a maximum number of pages for briefing packages, giving some flexibility for appendices. This should help sponsors be more concise, clear, and direct.

928
03:07:39.380 --> 03:07:43.509
TELEPHONE_USER: Thank you again for the opportunity to participate in this discussion today.

929
03:07:51.140 --> 03:07:55.519
TELEPHONE_USER: Thank you. Anne Eggiman from Tessera Therapeutics.

930
03:07:57.400 --> 03:08:03.559
TELEPHONE_USER: Our next presenter is Marcia Howard from the Consumer Health Care Products Association

931
03:08:03.810 --> 03:08:05.220
TELEPHONE_USER: and Marcia

932
03:08:19.780 --> 03:08:44.270
TELEPHONE_USER: Hi, my name is Marcia Howard, and I am an employee of the Consumer Healthcare Products Association, and they pay my salary. So, however, you infer that to be my financial disclosure. Hi! My name is Doctor Marcia Howard, and I'm Vice President of Regulatory and Scientific Affairs at the Consumer Healthcare Products Association or Chpa. Chpa is the leading Us-based Trade Association

933
03:08:44.270 --> 03:08:51.649
TELEPHONE_USER: for manufacturers of non-prescription or Otc. Medicines. Consumer medical devices and dietary supplements.

934
03:08:51.920 --> 03:09:04.109

TELEPHONE_USER: Our members have extensive experience with FDA meeting management. Since many of the Otc products consumers use for self-care are regulated under the new drug application or nda process.

935
03:09:04.310 --> 03:09:12.480
TELEPHONE_USER: Under this approval process. Drugs may be marketed directly as Otc medicines, or by prescription to non-prescription switch.

936
03:09:12.650 --> 03:09:16.280
TELEPHONE_USER: which is commonly referred to as Otc switch.

937
03:09:16.530 --> 03:09:24.710
TELEPHONE_USER: Our members are subject to the same review timelines, filing fees, and other PDUFA obligations as prescription drug manufacturers.

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03:09:25.120 --> 03:09:33.460
TELEPHONE_USER: But the Otc industry has significantly changed over the past 10 years, and many of our members no longer have prescription divisions.

939
03:09:33.510 --> 03:09:48.459
TELEPHONE_USER: Unfortunately, our members with Otc. Ndas do not have a way to provide relevant information and input to the agency about PDUFA meetings and metrics other than public forums like today, or written comments to the docket.

940
03:09:49.410 --> 03:10:17.830
TELEPHONE_USER: Otc nda products provide a meaningful difference in the health of Americans as an important sector of the regulated self-care industry. We ask FDA to consider ways that Chpa can play an active role in providing input to overall improvement for the Nda meetings process during the next PDUFA reauthorization cycle. And we intend to submit detailed written comments to the agency on today's topic for further consideration.

941
03:10:17.830 --> 03:10:19.529
TELEPHONE_USER: So thank you for your attention.

942
03:10:24.310 --> 03:10:29.649
TELEPHONE_USER: Thank you. Marcia Howard, from Consumer Health Care Products Association.

943
03:10:30.270 --> 03:10:43.549

TELEPHONE_USER: Our 3rd presenter is Gail Trocco, from the Pharmacon, Llc. And Gail is participating virtually so, if you can promote her to presenters so that she can

944
03:10:43.680 --> 03:10:45.050
TELEPHONE_USER: present her comment.

945
03:11:09.000 --> 03:11:12.490
TELEPHONE_USER: Is Gail able to to speak.

946
03:11:24.060 --> 03:11:29.449
Gail Trauco: Yeah, I think we're unmuted now. My name is Gail Traco. I'm the CEO of the farm. Con. Llc.

947
03:11:31.540 --> 03:11:32.379
Gail Trauco: We're on.

948
03:11:32.380 --> 03:11:34.979
TELEPHONE_USER: We can hear you now, so please go ahead.

949
03:11:35.140 --> 03:11:42.200
Gail Trauco: That's okay. Sorry about that. Y'all, it's it's remote. So we are a mobile nursing company

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03:11:42.220 --> 03:11:56.090
Gail Trauco: and specialize in decentralized clinical trials serving the United States. We have global partners as well, and I am so appreciative of having the opportunity to speak about the meetings. I think I had a slide with

951
03:11:56.090 --> 03:12:14.050
Gail Trauco: points on it. You've addressed everything that we felt that was key starting the meetings on time having a diverse audience, and I think one of the things that I haven't heard discussed to my satisfaction was how to create an inclusive environment, especially for our Lgbtq plus community.

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03:12:14.050 --> 03:12:30.749
Gail Trauco: We employ at least 2 mobile nurses who are transgenders, and as an employer I'm a big advocate for listening to their rights, and clinical trials are certainly not reaching these patients, and I have a feeling that many of the meetings that I have attended in the past over the last 30 years

953

03:12:30.750 --> 03:12:48.409
Gail Trauco: have not been attended as well as I would like to see for some of the diverse populations. How can you do that? You need to encourage diverse perspectives, make everyone feel welcome and valued by creating a safe and respectful place for all participants, encourage an open dialogue and active listening.

954
03:12:49.210 --> 03:13:10.280
Gail Trauco: You need to invite individuals from different backgrounds, cultures, genders, and abilities to participate in your meetings, share the meeting materials ahead of time, so that people can review it, have time to process it, and come prepared with their questions, and encourage equal participation by actively involving all attendees in the conversation.

955
03:13:10.280 --> 03:13:32.420
Gail Trauco: and give everyone the opportunity to speak and to speak their thoughts without feeling that they are being dominated by any process, or that they're being influenced by any gender bias. As far as language goes. We're a multi-language company. I speak 3 languages besides English. So I think it's important that that also be offered to participants as needed

956
03:13:32.480 --> 03:13:45.859
Gail Trauco: for some of the meetings I've attended. I have felt that security may not have been as good as it could. When my company plans meetings, we hire off duty law enforcement. We have a contract with a company in Birmingham, and we do this nationwide.

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03:13:46.020 --> 03:13:52.210
Gail Trauco: And I think that this day and time that that's extremely important to offer that additional level of security to people.

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03:13:52.360 --> 03:14:08.710
Gail Trauco: And then, as far as addressing unconscious bias, we need to make sure that as part of these meetings we are not imposing our own bias on attendees in the meeting that everybody's given an equal opportunity for facilitation techniques.

959
03:14:09.120 --> 03:14:13.659
Gail Trauco: Thank you for allowing me to present today, and I've enjoyed the meeting this morning.

960
03:14:17.290 --> 03:14:22.509
TELEPHONE_USER: Thank you, Gail Trocco from the Pharmacon, Llc. Thank you for your comments.

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03:14:24.380 --> 03:14:28.140
TELEPHONE_USER: so I would like to thank all of you for your comments

962
03:14:28.220 --> 03:14:31.830
TELEPHONE_USER: and for taking the time and effort to share them at this workshop.

963
03:14:32.210 --> 03:14:38.460
TELEPHONE_USER: This concludes today PDUFA’s 7 public workshop for meeting management best practices.

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03:14:39.050 --> 03:14:45.549
TELEPHONE_USER: I'm sure that everyone here appreciates all the presentations, perspectives, and discussions.

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03:14:45.750 --> 03:14:49.779
TELEPHONE_USER: and we look forward to receiving further comments to the public docket

966
03:14:50.660 --> 03:14:55.969
TELEPHONE_USER: again. Anyone from the public meeting is welcome to contribute through the public docket.

967
03:14:56.290 --> 03:15:03.609
TELEPHONE_USER: And again, a recording of this meeting and a transcript will be posted to FDA's webpage for this meeting.

968
03:15:04.020 --> 03:15:06.970
TELEPHONE_USER: Thank you for participating. And goodbye.

969
03:16:25.290 --> 03:16:37.800
TELEPHONE_USER: Oh, definitely right.