FDA Webinar: FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions

Moderator: Irene Aihie
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Coordinator: Welcome and thank you for standing by. At this time, all participants are in listen-only mode until the question and answer portion. If you would like to ask a question at that time, please press star followed by 1 on your touchtone phone. You'll be prompted to record your first and last name.

Today's conference is being recorded. If you have any objection, you may disconnect at this time.

Now I'll turn the call over to your host, Irene Aihie. Thank you, ma'am. You may begin.

Irene Aihie: Hello and welcome to today's FDA webinar. I am Irene Aihie of CDRH's Office of Communication and Education. On December 5, 2017 the FDA issued the final guidance titled FDA Categorization of Investigational Devices Exemption Devices to Assist the Centers for Medicare and Medicaid Services with Coverage Decisions. The purpose of the guidance is to modify the FDA's policy on categorization of IDE devices used in clinical investigations.

Today, Ken Skodacek will present an overview of the final guidance document. Following the presentation, we will open the line for your questions related to information provided during the presentation.

Additionally, there are other subject matter experts here with us today to assist with the Q&A portion of our webinar.

Now, I give you Ken.

Ken Skodacek: Thanks Irene for that introduction. My name is Ken Skodacek. I work in the Clinical Trials Program and in the Payer Communication Task Force and I'll be covering the slides for today's presentation.

Today's webinar presentation is divided into six sections. First, we will briefly discuss the general topic of investigational device exemption and then review the background and rationale for the guidance. Then we will review FDA's role in the overall process with a discussion of the category criteria, including some examples. We will then touch on the role of CMS in the process. We will also review how the category might change. And finally, we will conclude with a list of references with time for questions and answers.

At the end of this webinar, you should have a good understanding of how FDA assigns a CMS category to each IDE and how this category is subsequently used by CMS in making a coverage determination associated with the IDE.

First, we would like to provide some information about investigational device exemptions or IDE clinical investigations. FDA processes about 250 original IDE applications each year. An approved IDE allows a device to be used in a clinical study in order to collect safety and effectiveness data. Generally, an

IDE study is conducted to answer outstanding questions about device safety and effectiveness. However, the extent to which initial questions of safety and effectiveness are already addressed depends on many factors as each device and situation can be somewhat unique.

We'll discuss the phrase initial questions of safety and effectiveness in more detail in the subsequent slides. You can read more about the IDE clinical investigation regulations in section 21 of the Code of Federal Regulations, or CFR, Part 812.

Next, we'd like to provide some very basic information about FDA's decision-making process for IDEs. Approval of an IDE application indicates that FDA has determined that the sponsor has provided adequate data to support initiation of the study. It also indicates that FDA has determined that there are no subject protection concerns that preclude the initiation of the study after Institutional Review Board or IRB approval. Finally, it also indicates that FDA has determined that the benefit-risk profile for the study is favorable, with the benefits and value of information being obtained outweighing the risks of participation.

You can read more about these aspects of FDA's process in and the overall considerations in some previously issued guidance documents, including FDA Decisions for Investigational Device Exemption Clinical Investigations and Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions.

In the next part of today's webinar, we'll review the background and rationale for the guidance. This slide provides a high-level summary of what we mean when we talk about FDA's categorization of an IDE and the assignment of a CMS category.

In order to support the Centers for Medicare and Medicaid Services, or CMS, FDA categorizes IDE devices based on whether available data demonstrates that initial questions of safety and effectiveness have been resolved. Based on FDA's review of the information provided by the sponsor, IDE applications are assigned to one of two categories: Category A, experimental devices, or Category B, non-experimental investigational devices.

After our review of the relevant information, FDA communicates this categorization in our regulatory decision letters by assigning a CMS category. CMS then uses this categorization as one of several factors in its determination of which devices, as well as routine care and services, meet the requirements for Medicare coverage.

It's also important to be aware that there is some historical context about this topic in general. This slide includes some of the key milestones that have occurred over the past 20 plus years. FDA and the Health Care Financing Administration -- referred to as HCFA -- initially signed an interagency agreement in 1995. HCFA subsequently became and is now known as CMS. We will discuss the 1995 agreement in more detail on the next slide.

In 2010, FDA and CMS established a memorandum of understanding or MOU. The purpose of this MOU is to promote collaboration and enhance knowledge and efficiency by providing for the sharing of information and expertise between the agencies.

On January 1, 2015 changes were made to Medicare coverage requirements and CMS review procedures for IDE studies. And one of these changes included a shift from local Medicare administrative contractor, or MAC,

review to a centralized review conducted by the CMS Coverage Analysis Group, or CAG.

The agencies established another MOU in order to streamline facilitate the efficient categorization of investigational medical devices which ultimately supports the process that CMS uses to make Medicare coverage determinations. Finally, on December 5, 2017 FDA issued the final document on this topic.

There are three primary rationales for this guidance. First, previous FDA policy regarding the categorization did not adequately articulate criteria that are relevant to certain studies such as feasibility studies. Second, previous criteria did not consider all regulatory pathways -- for example, De Novo request. And third, previous policy did not contain sufficient guidance regarding how a category designation may change from A to B.

There are two secondary rationales for this guidance. As we mentioned before, CMS changed from local MAC review of IDE studies to a centralized review of IDE studies effective January 1, 2015. Interactions between FDA and CMS since that time have highlighted a need for changes to categorization in order to improve consistency. Together, all these rationales highlighted the need for an updated understanding of the process.

Next, we will compare and contrast the key elements of the 1995 interagency agreement relative to the new final guidance. The first column of this table summarizes the elements of the 1995 agreement. The second column summarizes the elements of the guidance.

There are three elements that have changed. First, the criteria have been simplified to ensure that the devices fall under the correct category. Second,

the final guidance provides an explanation of how a category change may occur. And third, the guidance provides a number of examples which should help to clarify how the revised criteria will be used by FDA staff.

The table also includes three elements that are not being changed from the 1995 interagency agreement. Specifically, these elements are that FDA review team makes the category designation, that the category designation is to be based on the degree to which initial questions of safety and effectiveness are resolved, and that categorization will then be used by CMS as part of its determination for whether or not items and services will be covered.

Now, we will review the revised criteria including in the guidance and highlight some examples. These criteria are the main focus of the guidance document and also the main focus of today's webinar.

Most importantly, we would like to emphasize that obtaining CMS coverage of an IDE clinical investigation is a two-step process. The FDA process is the first step. The sponsor would submit their IDE application to FDA. FDA then receives and reviews that application, primarily considering the requirements outlined in 21 CFR Part 812, the IDE regulations.

As one small but important part of that review FDA considers the available information and assigns a CMS category. And that assignment is included in the IDE regulatory decision letter for studies that are fully approved or approved with conditions.

As we mentioned previously, FDA assigns each IDE to one of two categories. Before we provide the definition of category A, it is important to note that these definitions are provided in the CMS regulations. We provided the text from the regulations here.

Category A, experimental, is assigned for a device for which absolute risk of the device types has not been established -- that is, initial questions of safety and effectiveness have not been resolved -- and the FDA is unsure whether the device type can be safe and effective. Specifically, this text appears in the CMS regulations 42 CFR Part 405.201(b) and has not changed.

We will now review the text in the guidance, which is our interpretation of the previously referenced regulations. We will walk through each of these three criteria individually.

Please note than an IDE is assigned category A if one or more of the following criteria are met -- the first criterion for category A is no PMA approval, 510(k) clearance, or De Novo request has been granted for the proposed device or similar devices, and data on the proposed device or other similar devices do not resolve initial questions of safety and effectiveness and FDA is unsure whether the device type can be safe and effective.

We have summarized the criterion using more concise text within the box. No prior approved cleared device and available data do not resolve initial questions of safety and effectiveness. We'll explain how this text will help you to understand all the criteria momentarily.

An IDE is assigned Category A if one or more of the following criteria are met -- the second criterion for category A is the proposed device is being studied for a new indication or new intended use for which information from the proposed or a similar device related to the previous indication or intended use does not resolve initial questions of safety and effectiveness. Available nonclinical and/or clinical data on the proposed device or similar devices relative to the new indication or intended use also do not resolve these

questions and FDA is unsure whether the device type can be safe and effective.

Again, we have summarized this information using more concise text within the box. New indication or new intended use. Available data do not resolve initial questions of safety and effectiveness.

An IDE is assigned category A if one or more of the following criteria are met -- the third criterion for category A is the proposed device has different technological characteristics compared to a legally marketed device, and information related to the marketed device does not resolve initial questions of safety and effectiveness for the proposed device. Available clinical and non-clinical data on the proposed device or similar devices also do not resolve these questions and FDA is unsure whether the device type can be safe and effective.

Again, we have summarized this information using more concise text within the box. New technological characteristics compared to approved/cleared devices. Available data do not resolve initial questions of safety and effectiveness.

This slide summarizes the three different criteria for category A. An IDE is assigned category A if one or more of the three criteria are met. The first criterion would apply when there is no prior approved cleared device and available data do not resolve initial questions of safety and effectiveness.

The second criterion would apply when there is new indication or new intended use, and again, available data do not resolve initial questions of safety and effectiveness.

The third criterion would apply when there are new technological characteristics compared to approved cleared devices and available data do not resolve initial questions of safety and effectiveness.

Please note that in all cases, the available data including non-clinical and clinical data from proposed device or similar devices does not resolve initial questions of safety and effectiveness. In plain language, category A is typically assigned to devices that are new and significantly different from or used in different ways from devices that are already commercially available and already being used within our healthcare system.

With these new devices, there is not sufficient, non-clinical and clinical information available to resolve initial questions of safety and effectiveness.

Now we'd like to review two selected examples for category A from the guidance. One example is a device that is completely novel and has no or limited previous human use and there are initial questions of safety and effectiveness. There is adequate non-clinical information to support initiation of an early feasibility study that will provide data to inform the potential device design or procedural improvements.

Another example is a new device. The initial questions of safety have been answered with a submission of non-clinical data and short-term clinical data. However, additional performance data will be needed to resolve questions related to effectiveness. Please note the distinction between safety and effectiveness in this example.

As we mentioned previously, FDA assigns each IDE to one of two categories. Before we provide the definition for category B, it is again important to note

that these definitions are provided in the CMS regulations. We provided the text from the regulation here.

The other category is category B, nonexperimental investigational. And is assigned for a device for which the incremental risk is the primary risk in question -- that is, initial questions of safety and effectiveness of that device type have been resolved -- or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type.

Specifically, this text appears in the CMS regulations 42 CFR Part 405.201(b) and has not changed.

We will now review the text in the guidance which is our interpretation of the previously referenced regulations. And we will walk through each of the three criteria individually.

Please note that an IDE is assigned category B if one or more of the following criteria are met. The first criterion for category B is no PMA approval, 510(k) clearance, or De Novo request has been granted for the proposed device or similar devices; however, available information -- for example, feasibility study data -- from the proposed device or a similar device resolves the initial questions of safety and effectiveness.

We have summarized the criterion using the more concise text within the box. No prior approved/cleared device. However, available data resolves initial questions of safety and effectiveness. We will explain how this text will help you understand all the criteria momentarily.

An IDE is assigned category B if one or more of the following criteria are met. The second criterion for category B is the proposed device is being studied for a new indication or new intended use; however, information from the proposed or a similar device related to the previous indication or intended use resolves the initial questions of safety and effectiveness. In some cases, additional non-clinical and/or clinical data on the proposed device may also have been used to resolve these questions.

Again, we have summarized this information using more concise text within the box. New indication or new intended use. However, available data resolves initial questions of safety and effectiveness.

An IDE is assigned category B if one or more of the following criteria are met. The third criterion for category B is the proposed device has similar technological characteristics compared to a legally marketed device, and information related to the legally marketed device resolves initial questions of safety and effectiveness for the proposed device. In some cases, additional nonclinical and/or clinical data on the proposed device may also have been used to resolve these questions.

Again, we have summarized this information using more concise text within the box. Similar technological characteristics compared to approved/cleared devices. And available data resolves initial questions of safety and effectiveness.

This slide summarizes the three different criteria for category B. An IDE is assigned category B if one or more of the following three criteria are met.

The first criterion would apply when there is no prior approved or cleared device. However, available data resolves initial questions of safety and

effectiveness. The second criterion would apply when there is a new indication or a new intended use. However, available data resolves initial questions of safety and effectiveness.

And the third criterion would apply when there are similar technological characteristics compared to approved/cleared devices and available data resolves initial questions of safety and effectiveness.

You might notice that the initial bullet in in each box are similar to the initial bullets from category A. However, please note that in all cases the available data, including nonclinical and clinical data from the proposed device or similar devices, does resolve initial questions of safety and effectiveness.

In plain language, category B is typically assigned to devices that are not new and that are significantly similar to or used in similar ways to devices that are commercially available and already being used within our healthcare system. With these devices, given their similarity to other devices, there is sufficient nonclinical and clinical information available to resolve initial questions of safety and effectiveness.

Now we would like to review two selected examples for category B from the guidance. One example is a device that is similar to other devices on the market. In this example, a new device will be studied for an indication for which substantial safety and effectiveness information exists from other similar devices of the same type that are used for the same or similar indication. Clinical information from similar devices and non-clinical test data from the new device that have been provided can answer initial safety and effectiveness questions regarding this indication.

Another example is an approved device for a new indication. In this example, an approved device will be evaluated for a new indication. Data exists on the approved device for a similar indication and non-clinical data have also been supplied such that initial questions of safety and effectiveness related to the new indication have been resolved.

The new study to be conducted will provide further data regarding the device performance for this new indication.

Next, we will briefly review some aspects of the CMS process. As we mentioned before, obtaining CMS coverage of an IDE clinical investigation is a two-step process. The FDA process is the first step. Unfortunately, many sponsors mistakenly believe that no further action is necessary and it's important for sponsors to understand that CMS has an entirely separate application and review process.

This process is not the focus of the FDA's guidance and is therefore not the primary focus of today's webinar. However, we strongly encourage sponsors to read more about the application process and coverage criteria on the CMS website using the link on this slide.

Acknowledging that you can't click on the link during the webinar, you can search Google for CMS IDE coverage or Medicare coverage related to IDE trials. You can also review the list of approved IDE studies using the link within the diagram.

Again, for clarity this slide emphasizes that there are two steps in the FDA process -- the FDA review process and the CMS review process. If a sponsor would like to obtain Medicare coverage for their IDE clinical investigation,

then we recommend that the sponsor must consider both steps and the associated criteria when designing their IDE clinical investigation.

We have a representative from CMS here with us today in case you have questions about the CMS process.

Ultimately there are two potential results if you request and are granted coverage for your IDE clinical investigation. If CMS grants coverage for an IDE clinical investigation that is designated as category A by FDA, then that designation will allow coverage of routine care items and services furnished in the study, but not the category A device, which is statutorily excluded from coverage.

If CMS grants coverage for an IDE clinical investigation that is designated as category B by FDA, then that designation will allow coverage of the category B device and the routine care items and services in the trial.

In both cases, it is possible to obtain coverage for routine care items and services. However, only category B allows for coverage of the investigational device itself. It is also important to note that in both cases, additional testing and procedures that are required by the clinical protocol, but not routine care items and services would not be covered by CMS.

Next, we will discuss how the assigned CMS category might be changed. In some cases, the understanding of the investigational device and the associated support data may evolve over time. Clinical and/or non-clinical data gathered during the study may resolve initial questions of safety and effectiveness.

Alternatively, an IDE that was assigned category A may have been completed, resolving initial questions of safety and effectiveness.

The bullets on this slide elaborate on the data that may support a change from category A to category B. Some examples include but are not limited to peer-reviewed studies on the same or a similar device, premarket or post market data from studies conducted outside the US on the same or a similar device, reference to commercialization of a device of a similar type, preliminary clinical data on the device -- for example, initial data from a staged study or a feasibility study -- or additional non-clinical data on the same or a similar device may be included as supportive information.

We'd like to review two selected examples for changing the category from the guidance. For the first example, a novel insertion procedure will be used to place an already approved or cleared device, and there are initial questions of safety and effectiveness regarding the novel insertion procedure that have not been resolved.

In these, questions of safety and effectiveness may be answered in a short timeframe with a limited number of subjects in the context of a larger clinical study. Therefore, the device will be evaluated in a staged clinical study where the first stage falls under category A.

If the initial questions of safety and effectiveness are resolved and then the study continues, the device may be recategorized to category B.

For the second example, a device is currently being evaluated in a clinical study and has been designated category A. While the study is being conducted, clinical study results for similar devices become available which resolve initial questions of safety and effectiveness for this device. For example, FDA staff might refer to the summary and safety and effectiveness document that summarizes the clinical study results for this similar device.

As the final part of today's webinar, we would like to provide some references and links in case you want to read more about the variety of topics that we have covered here today.

Before we present the references and conclude today's webinar presentation, we'd like to mention that CDRH has established a Payer Communication Task Force. The group facilitates early communications between device manufacturers, payers, and healthcare technology assessment organizations to potentially shorten the time between FDA approval or clearance and coverage decisions.

It is important to note that our focus is on coverage by both public and private payers once the device is commercially available outside of the IDE clinical investigation. Our team also coordinates the FDA/CMS Parallel Review program and other opportunities for public and private payer engagements. You can click on the link at the top of the page to learn more about our programs.

You can also contact us via email if you have any questions. For general questions, please use our general email address. For questions specific to parallel review, please use the applicable email address.

Here are some references and links that you can review later. And here are some additional references and links.

This concludes my presentation. We can now open the webinar to questions, which we'd be happy to answer for you. In addition, we have three other individuals with me here today. Joining me today are Dr. Soma Kalb, Director of the IDE Program, Dr. Owen Faris, Director of the Clinical Trials Program,

and Dr. Daniel Canos who's representing the Coverage Analysis Group at CMS. Daniel is familiar with the overall process and criteria that CMS uses in making coverage decisions for investigational devices.

Coordinator: Thank you very much, sir. If you would like to ask a question, please press star followed by 1 on your touchtone phone. You will be prompted to record your first and last name and called on at your turn. Please do check that your mute button is turned off before recording your name.

Should you decide to withdraw your request, please press star followed by 2. One moment to give participants time to queue up.

Ken Skodacek: We do have some initial questions prepared. I'm going to turn it over to Dr. Soma Kalb to start us out with some of those questions.

Soma Kalb: Thank you, Ken. The first question that we have -- these are from questions that we commonly received -- the first one is, "What can an IDE sponsor do if they disagree with the categorization made by FDA during the review of the IDE application?"

Ken Skodacek: Thanks, Soma for that question. So as I mentioned before, the guidance talks a little bit about how to make a change in that category or the process that a sponsor might use. What I would suggest if they want to make that change is they could simply pick up the phone, contact the reviewer.

At the end of every IDE regulatory decision letter, there's a phone number provided of the reviewer. Pick up the phone. Have a conversation with them to better understand why they assigned a certain category. And if there may be some additional information that wasn't included in your original IDE

application or some additional clarification would be necessary, they could submit an IDE supplement and request that the IDE be recategorized.

But the easiest way I think is initially just to pick up a phone, have that conversation to better understand the rationale for how we made the categorization.

Soma Kalb: All right. So I have another question here, "When preparing the protocol to meet those FDA's needs and CMS' needs, how do we get feedback from those agencies?"

Ken Skodacek: Great question. So I think what we learned from some of our conversations with a lot of different sponsors, in some cases sponsors are actually going informally to CMS first and trying to understand what the requirements are from CMS. So they might approach CMS informally.

Another option would be to ask FDA to consider setting up a pre-submission meeting, so setting up an opportunity for FDA to give you feedback about your clinical trial design. And then either contacting CMS and asking them to join that meeting or asking the FDA staff for us to contact CMS to join the meeting.

In either case, I think the overall idea is to figure out how to bring FDA and CMS together during your pre=submission meeting when you're planning your overall trial and selecting your end points, indications for use, enrollment criteria, and engage both agencies and allow both agencies to give you feedback before you design your clinical trial and before you submit your IDE.

Woman: We'll take our first question.

Coordinator: Thank you. We have a question from (Kelly Gordon).

(Kelly Gordon): Hi. For non significant risk devices meeting the abbreviated IDE requirements under 812.2(b), how will the sponsor know what category the device falls into if there's no IDE decision letter provided?

Woman: One second while we get that answer for you.

Ken Skodacek: Thank you, (Kelly) for that question. What we'd like to do -- that's a great question -- we'd like you to do is if you could follow up with an email to DICE after the end of the webinar and we'll follow up and get a good answer for you.

(Kelly Gordon): Okay. Thank you.

Coordinator: If anyone else would like to queue up and ask their question over the phone line, please press star followed by 1 and record your name after the prompt.

Soma Kalb: All right. While we are seeing if there are additional questions on the phone, one question that we wanted to provide some information on is, what additional information could be in the application to CMS?

Daniel Canos: This is Daniel Canos from the CMS Coverage Analysis Group. So Ken during his presentation provided a hyperlink to the CMS IDE web page that provides details, what is required in the submissions. Sponsors with FDA, approval letters dated January 1, 2015 or after can submit a request.

Many times we get requests from sites, individual investigator sites, but we actually require the sponsor of the study to submit those. We'll redirect those

to the actual sponsor. We require an FDA approval letter, IDE study of protocol, the IRB approval letter, national clinical trial number, and supporting materials.

Also listed on the site are the ten criteria that are required to be met for CMS coverage. And as you're asked what's being included in protocol, that would be helpful for our review. Many times, study protocols and coverage request letters don't provide a detailed study protocol that describes the method and timing of release of results for all prespecified outcomes. And also their release of negative outcomes that should be hastened if the study is terminated early.

The protocols will cover release of the data to the FDA, but CMS makes its decisions based on publicly available information, so we require the protocol to detail how such findings will be published, put in the public realm.

Another element that at times can be lacking within the study protocols that facilitate our review is also covered in the criteria, which is number ten. The protocols need to describe how Medicare beneficiaries may be affected by the device under investigation and how the results are or are not expected to be generalizable to our population. We'll at times turn down IDE protocols where for coverage where it is not clear how the device actually affects our beneficiary population.

Woman: Thank you. We'll take our next question.

Coordinator: Thank you. We do have a question from (Chandra Branham). Your line is now open.

(Chandra Branham): Hi. This is (Chandra Branham) from AdvaMed. And I think this question is probably for Daniel Canos. But I wondered if you could speak to the experience of those devices that transition from category A to category B. I know the guidance was just finalized, but the program has been in effect for a while. Have you seen devices actually make that transition? Or has that happened yet? I'm curious what the experience has been.

Daniel Canos: Thank you. Very good question. So we have worked with sponsors and the FDA on devices that have transitioned from the category A and category B. As Ken mentioned during I think the first response to the first question, that FDA as well as CMS are open to, you know, collaboratively and interactively reviewing such data.

And when we approve those devices, the studies, CMS is open to interactively meeting with the sponsor -- and we encourage that meeting to include the FDA as well -- to review the data as it's complied so that we can, you know, weigh in early as the data is accumulated and provide feedback when CMS would be open to considering that data to be enough and sufficient to cover that study if it were to be submitted to CMS as a category B device.

And I would say of the ones that have transitioned, you know, we have definitely entertained an interactive approach to that review. The idea is to…

((Crosstalk))

(Chandra Branham): Can you say anything about…

Daniel Canos: The idea is to streamline the process so that you're not going to FDA for categorization only for CMS to turn it down if it were to come across our desk. So I think I really encourage an interactive process in that.

(Chandra Branham): Thank you. Can you say anything about the number of those that have transitioned? I mean, is it…

((Crosstalk))

Daniel Canos: That I can't.

((Crosstalk))

Daniel Canos: Yes. That exact number, I do not have.

(Chandra Branham): Okay. Thank you.

Coordinator: We do have another question. (Brooke Laughlin) your line is open.

(Brooke Laughlin): Hi. Yes, we were just calling to wonder if changes are made to the protocol because there's an iteration in the device, does that require a new CMS application? Or what changes kind of constitute requiring a renewal of the CMS application?

Daniel Canos: Also another good question. So we really don't require submission of a new protocol for review unless it substantially affects the conduct of the study and, you know, ability to assess those primary endpoints. So we are open to receiving revisions to the protocol as FDA approves them and also adding that to the file, but we really don't require you know, we don't have a re-review of that IDE study unless the actual primary intent, primary purpose of the study, changes due to a protocol revision.

(Brooke Laughlin): Okay. Thank you.

Coordinator: At this time, we have no further questions. I'll turn it back over to you, Ms. Aihie.

Soma Kalb: I wanted to address our last question that we had prepared initially that we receive frequently. One is that if a study is designated as category A and initial questions of safety and effectiveness are resolved during the conduct of an IDE, does FDA automatically change the category or is it only by request of the sponsor?

Ken Skodacek: That's a good question. So yes, everything has to come in through a supplement to us. So we don't monitor the connection between all the various IDE supplements we get, right? So Daniel mentioned that they only want to see major changes in the protocol. But we see a lot of different IDE supplements for changes in the protocol, changes in the device, changes in manufacturing, changes in the status of the study -- maybe they've completed enrollment -- but we don't necessarily tie those to the category.

So if you want to change the category based on data you've collected in the trial, you have to submit a supplement to make the request for that change.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH Learn web page at www.fda.gov/training/cdrhlearn by Wednesday, January 24th.

If you have additional questions about today's presentation, please use the contact information provided at the end of the slide presentation.

As always, we appreciate your feedback. Following the conclusion of the webinar, please complete a short 13 question survey about your FDA CDRH webinar experience. The survey can be found at fda.gov/cdrhwebinar immediately following the conclusion of today's live webinar.

Again, thank you for participating and this concludes today's webinar.

Coordinator: Thank you for your participation. All parties may disconnect at this time.

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