Final Guidance: Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions
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CDR Kim Piermatteo: Hello everyone and welcome to today's CDRH webinar. This is Commander Kim Piermatteo of United States Public Health Service, and I serve as the Education Program Administrator in the Division of Industry and Consumer Education within FDA's Center for Devices and Radiological Health. I'll be the moderator for today's webinar.

Our topic today is the final guidance titled, Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions, which was issued on December 4, 2024. This guidance provides recommendations on the information to include in a Predetermined Change Control Plan, or PCCP, in a marketing submission for a device that includes one or more artificial intelligence-enabled device software functions.

I'd now like to introduce our presenters for today's webinar: Jessica Paulsen, Associate Director for Digital Health within CDRH's Office of Product Evaluation and Quality, or OPEQ; Dr. MiRa Jacobs, Division Director of the Division of Digital Health Policy within CDRH's Digital Health Center of Excellence; and Ayobami Adebowale, Policy Analyst in the Division of Digital Health Policy within CDRH's Digital Health Center of Excellence, as well.

We'll begin with a presentation from our presenters and then field your questions about this guidance. Before I turn it over to our presenters, I'd like to provide a few reminders. First, please make sure you've joined us through a Zoom app and not through a web browser to avoid technical issues.

Second, the intended audience for this webinar is industry. Trade press reporters are encouraged to consult with the CDRH trade press team at CDRHTradePress@fda.hhs.gov. And members of national media may consult with FDA's Office of Media Affairs at FDAOMA@fda.hhs.gov.

Third, if you would like to follow along with today's presentation, you may access printable slides from this webinar's events page or CDRH Learn under the section titled Specialty Technical Topics and the subsection Digital Health.

And lastly, we look forward to interacting with you during the live question and answer segment of today's webinar. If you have a question, please wait to raise your hand at the end of today's presentation to get into the queue.

Thank you all again for joining us. I'll now turn it over to Jessica to start today's presentation.

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Jessica Paulsen: Thanks for the introduction, Kim. Hi everyone and thank you for joining today's webinar to discuss our recently finalized guidance.

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Jessica Paulsen: On December 4, 2024, we issued our final guidance titled Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions.

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Jessica Paulsen: For today's webinar, we have several learning objectives. First, we'll provide a summary of the comments we received and explain changes that were made from the draft guidance to the final guidance. After that, we'll describe the scope and policies of the final guidance.

Then, we'll dive into the specific recommendations for the information to be included in a predetermined change control plan in a marketing submission for an artificial intelligence-enabled device, which we'll refer to as a PCCP and an AI-enabled device in this webinar.

Finally, we'll explain FDA's policy on the types of modifications that may be included in PCCPs for AI-enabled device software functions, or AI-DSFs.

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Jessica Paulsen: FDA has a long-standing commitment to develop and apply innovative approaches to the regulation of medical device software and other digital health technologies to ensure their safety and effectiveness and this includes device software functions that incorporate AI.

In the 2019 discussion paper, we introduced the term and the contents of a predetermined change control plan and described how a total product life cycle-based approach can be used to assure that an AI/ML-enabled devices would remain safe and effective while changing over time.

Then, in our 2021 action plan, we described a holistic, strategic approach to AI/ML-enabled devices, ensuring their safety and effectiveness while supporting responsible innovation in this space. In addition to a focus on good machine learning practice and transparency about AI/ML-enabled devices, the action plan reaffirmed the agency's commitment to continuing to develop the regulatory framework for these devices.

Then, in response to comments received on the discussion paper and the action plan, we developed the draft guidance on marketing submission recommendations for a PCCP for AI/ML-enabled device software functions, which issued in April of 2023. And now, we've issued final guidance on this topic that we're excited to discuss with you today as another step towards applying innovative approaches to the regulation of AI-enabled devices.

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Jessica Paulsen: Before transitioning to the content of the final guidance, I would like to briefly highlight the Food and Drug Omnibus Reform Act, which added section 515C to the Federal Food, Drug, and Cosmetic Act, or FD&C Act. And it includes specific provisions for PCCPs for medical devices.

So, Section 515C provides that FDA may approve or clear a PCCP reviewed in a premarket approval, or PMA, or a premarket notification, referred to as 510(k). Section 515C also clarified that changes to a device that are consistent with an approved or cleared PCCP do not require a subsequent supplemental application.

And notably, this provision applies to all device types. It is not specific to only software or AI-enabled devices. FDA has provided its interpretation of our statutory authorities, including these provisions for PCCPs in the draft guidance on predetermined change control plans for medical devices issued this past August of 2024, as well as in this final guidance, which is specific to and focused on PCCPs for AI-enabled devices.

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Jessica Paulsen: Now, in the next few slides, we're going to summarize the comments that were received in the docket for the draft version of the guidance, and then note the changes that were made from the draft to the final version of this guidance.

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Jessica Paulsen: The comments that were received from the public were largely requests for clarification on the content of the guidance. The requests for clarification were on topics such as the scope, including the applicability of this guidance to combination products, as well as to devices that are not AI-enabled. We also received requests for clarification on terms such as training, tuning, and testing data.

We received feedback requesting additional detail on the types of information related to the PCCP to include in the device's labeling, as well as in publicly available summaries. We also received requests for clarification regarding what submission types may be used to establish or modify a PCCP, as well as how a modification should be implemented to a device consistent with an authorized PCCP.

We received requests for inclusion of additional types of modifications in a PCCP. And finally, we did receive requests for clarification regarding how manufacturers should conduct post market surveillance activities as part of their PCCP. In addition to these topics, there were a number of requests to provide additional examples in Appendix B.

Slide 10

Jessica Paulsen: So, in response to the comments received, FDA made several changes from the draft to the final version of the guidance. And we'll cover these changes as we present the policy in this final guidance, but as you can see, we clarified the guidance in response to the comments that we received, including, for example, the scope of the guidance, the marketing submission types for establishing and modifying PCCPs, and additional modification types for inclusion in a PCCP, among others.

So, throughout this presentation, we will highlight those changes using a white arrow update symbol. And those of you who are familiar with the recent draft guidance, Predetermined Change Control Plans for Medical Devices, you may be wondering if there are any differences between that draft guidance and this final guidance. So, throughout the presentation, we will identify content that is specific to this final guidance and AI-enabled devices using the dark blue flag symbol. And finally, we are also highlighting some general tips for sponsors using a yellow star.

Slide 11

Jessica Paulsen: So before describing the policies in the final guidance, we wanted to review some of the terms and definitions that are used in the guidance.

First, the terms artificial intelligence, or AI, and machine learning, or ML were added in the final guidance to align with the executive order on AI. So, AI is defined as a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments.

ML is defined as a set of techniques that can be used to train AI algorithms to improve performance at a task based on data. So importantly, one change that was made from the draft guidance was that the term ML-enabled device software functions, or ML-DSF, was generalized to artificial intelligence-enabled

device software functions, or AI-DSF throughout the final guidance. And AI-DSF is a device software function that implements an AI model. So, we acknowledge that the majority of premarket submissions for devices containing PCCPs that FDA has reviewed are submissions for devices that incorporate ML, a subset of AI. And many of the recommendations in the guidance remain tailored to devices that incorporate ML.

However, we do intend for the recommendations in this guidance to be broadly applicable to all AI-enabled devices. And to that end, we've broadened the scope and the terminology used throughout the final guidance.

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Jessica Paulsen: We also have defined the terms PCCP and authorized PCCP, which are important terms that were not modified in the final version of the guidance. So, a PCCP is considered the documentation describing what modifications will be made to the device and how the modifications will be assessed. So, as described in the guidance, we recommend that a PCCP comprises three components, including a description of the modifications, the modification protocol, and an impact assessment.

So, we'll revisit each of these components and discuss recommendations for each component during the presentation today. And it's also important to note that a PCCP is intended to only include proposed changes that would otherwise require a new marketing submission. And an authorized PCCP is one that has been reviewed and established through a device marketing authorization. And an authorized PCCP is a technological characteristic of the authorized device with which it was established.

Slide 13

Jessica Paulsen: Now, let's discuss the scope of the final guidance. So, as envisioned in our 2021 action plan, this final guidance is intended to provide recommendations for AI-DSFs that a manufacturer intends to modify over time. As I noted earlier, the dark blue AI PCCP flags are intended to highlight content that is unique to the AI PCCP final guidance in comparison to the PCCP draft guidance.

So, in this final guidance, we provide recommendations on what information should be included in a PCCP as part of a marketing submission, specifically for an AI-enabled device. Modifications included in a PCCP are those device modifications that generally would otherwise require a new marketing submission.

So, these recommendations are applicable to devices that are or include an AI-DSF, including the device constituent part of device-led combination products when the device constituent part is or includes an AI-DSF. We highly encourage early engagement with FDA in those scenarios.

So, it's important to note that the PCCP remains a fully optional mechanism within a marketing submission for a device that is or includes an AI-DSF. The PCCP mechanism is meant to provide an available route for introducing certain planned significant changes to an AI-DSF.

So again, devices that are or include an AI-DSF are not required to include a PCCP as part of their marketing submission and may continue to implement such device changes through additional marketing submissions to FDA as applicable.

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Jessica Paulsen: It's also important to note what is not in the scope of this final guidance. So first, this guidance is not applicable to device modifications that do not require a new marketing submission. This final guidance is also not intended to provide a comprehensive means of delineating the types of modifications that the agency would consider acceptable in a PCCP.

We've included some discussion on the types of changes we believe may generally be appropriate to include in a PCCP and some considerations regarding the types of changes that may not be appropriate

to review in a PCCP as well. Additionally, this final guidance is not intended to provide a complete description of what may be necessary to include in a marketing submission for an AI-DSF. Instead, the final guidance provides general recommendations and examples for a PCCP for an AI-DSF. Since each device under review may be unique and may have a number of different considerations that affect the needs of a marketing submission and the course of a review, it should be understood that the FDA review team responsible for reviewing a device and its PCCP will determine whether the scope of the proposed modifications is appropriate for inclusion in a PCCP, and what evidence and information would ensure that the AI-DSF with that PCCP remains safe and effective.

So, with that, I am going to hand it over to Bami, who will provide an overview of our policy for PCCPs for AI-DSFs.

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Ayobami Adebowale: Thanks, Jessica. Let's dive in.

Slide 16

Ayobami Adebowale: The content in the next few slides may be familiar to some of you, as the policy for PCCPs in this final guidance remains substantially similar to that of the draft guidance. It is also the same as the policy for PCCPs in the draft PCCP guidance.

However, I will reiterate some of the highlights of the policy and describe some changes we've made from the draft to the final version of this guidance. As Jessica noted earlier, an authorized PCCP is intended to specify plan modifications that, if not included in a PCCP, could otherwise require a new marketing submission.

Modifications that are part of an authorized PCCP for an AI-DSF can be implemented without triggering the need for a new marketing submission. In other words, provided the changes were detailed in and implemented according to the authorized PCCP, which includes both the change meeting pre-specified performance criteria and being implemented per the methods defined in the PCCP. Then, the modified device will not need to be reviewed again by FDA.

On the other hand, those modifications that are not part of an authorized PCCP could require a new marketing submission depending upon the change. Consistent with current policy for authorized devices that do not have a PCCP, plan modifications that were not specified in an authorized PCCP should be reviewed by the manufacturer and implemented pursuant to 21 CFR 807.81(a)(3) and 21 CFR 814.39(a), and in accordance with the device modifications guidances, which may include that a new marketing submission is required for the modified device prior to making the change.

Slide 17

Ayobami Adebowale: Now, let's jump into the components of a PCCP as part of a marketing submission for a device. A PCCP is structured into three components. A description of modification, a modification protocol, and an impact assessment. Together, these three elements describe what the manufacturer intends to modify, how they will make those modifications while ensuring the device remains safe and effective, and the benefits and risks of the proposed modifications and how identified risks will be mitigated.

The description of modifications section of a PCCP is where each specific modification a manufacturer plans to implement with an authorized PCCP is delineated. It includes the specifications for the characteristics and performance of the planned modifications to the AI-DSF.

The modifications protocol section of a PCCP describes the methods that will be followed when developing, validating, and implementing the modifications described in the description of modifications to ensure the device remains safe and effective. Every modification detailed in the description of

modifications should have corresponding methods and metrics for implementation in the modification protocol.

The impact assessment section of the PCCP provides an assessment of the benefits and risks of each modification outlined in the description of modifications, as well as the collective impact of those modifications. In the impact assessment, manufacturers should also provide a discussion of how the activities proposed in the modification protocol mitigate the risks that are identified in the impact assessment. The impact assessment should help to make clear how these activities help to reasonably assure that the device, with any modifications implemented according to the authorized PCCP, will remain as safe and effective as the version of the device without any such changes.

Slide 18

Ayobami Adebowale: These three components described the description of modifications, modifications protocol, and impact assessment should be included in a PCCP as a standalone section in the marketing submission, importantly, with a title and version number. The PCCP should also be noted in the cover letter and table of contents for your marketing submission, as this is very helpful for reviewers to be able to easily and quickly identify that a submission contains a PCCP.

Finally, the PCCP should be described and referenced as appropriate in other sections of your marketing submission, which may include your device description, labeling, and other relevant sections related to safety and effectiveness, or substantial equivalence.

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Ayobami Adebowale: In the next few slides, I will discuss how to establish, modify, and implement an authorized PCCP. I'll start with how a PCCP can be established, including through what marketing submission types. A PCCP should be reviewed and established as part of a marketing authorization for a device, and once it has been established, is referred to as an authorized PCCP.

Only those modifications included in an authorized PCCP for a device may be implemented for that device without triggering the need for a new marketing submission. In the final version of this guidance, we included the submission types that are generally appropriate to establish a PCCP, including various PMA applications or supplement types, 510(k) submission types, and De Novo requests.

For 510(k) submission types, in making a determination of substantial equivalence where the predicate device was authorized with the PCCP, the subject device must be compared to the version of the predicate device cleared or approved prior to changes made under the PCCP. Importantly, submission types for which FDA does not make an affirmative decision would not be appropriate to establish a PCCP.

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Ayobami Adebowale: Next, let's discuss how to modify a previously authorized PCCP. FDA believes that modifications to an authorized PCCP will generally be changes to the device that would otherwise require a new marketing submission. As such, changes will generally significantly affect the safety or effectiveness of the device. Therefore, modifications to a PCCP will generally need to be reviewed and established as part of the marketing submission for the modified device. It is also important to note that an authorized PCCP is only available to the version of the authorized device with which it was established.

So, if an authorized device is significantly modified, except for the modifications specified in the authorized PCCP, a new marketing submission is required for the modified device, including the content necessary to establish or re-establish a PCCP for the modified device. Many of the same submission types, including PMA supplement and 510(k) submission types, are generally appropriate to modify a previously authorized PCCP.

In the final version of this guidance, we also specify that a special 510(k) may be an appropriate submission type to modify a previously authorized PCCP if the modifications to a PCCP are changes to the manufacturer's own device and PCCP, and well-established methods are available to establish the change to the PCCP.

In general, if you intend to modify a previously authorized PCCP, it can be very helpful to FDA if you provide a summary of the changes to the authorized PCCP. And if possible, attract changes or red line versions compared to the authorized PCCP.

Slide 21

Ayobami Adebowale: Once a device has an authorized PCCP, the modifications detailed in it can be implemented. In the final guidance, we've provided this flowchart to help illustrate how a manufacturer should utilize their authorized PCCP to implement device modifications. This flowchart and process has not changed from the draft of this guidance. When implementing a modification to a device with an authorized PCCP, a manufacturer should first consider whether the particular modification is or is not consistent with the authorized PCCP.

As described in the flowchart, this means first, is the modification specified in the description of modifications? And second, is the modification implemented in accordance with both the methods and performance specifications that were included in the modification protocol? If so, a new marketing submission is not necessary.

The modification can be implemented in accordance with the modification protocol. The manufacturer should then document that modification and the analysis in accordance with the manufacturer's quality system. If the particular modification is not consistent with the authorized PCCP, including if the modification is not included in the authorized PCCP, or if the modification is included in the authorized PCCP but is not implemented in accordance with the methods or performance specifications that were included in the modification protocol, the manufacturer should then proceed to evaluate the particular modification in accordance with applicable FDA requirements. And after consulting the device modifications guidance, to determine if a new marketing submission is required. It is possible a new marketing submission may not be required, which may lead to implementation of the modification and documentation of that modification and the analysis in accordance with the manufacturer's quality system.

However, in the majority of cases, because modifications included in a PCCP are those that would generally otherwise require a new marketing submission, it's likely that a new marketing submission will be required before the manufacturer can implement the change. If a new marketing submission is required, the manufacturer must submit the appropriate marketing submission before the modified device is marketed. Further, if the manufacturer wishes to establish a PCCP with the modified device, that PCCP must be included as part of the new marketing submission, so both the modified device and PCCP can be authorized together.

Slide 22

Ayobami Adebowale: Now, let's transition to updated recommendations regarding labeling and public decision summary content related to PCCPs in the final version of this guidance. The final guidance has been revised to include general recommendations on the information to include in the labeling related to a device and its authorized PCCP in an effort to promote transparency so users can use the device safely and effectively and continue to do so as the device changes in accordance with the authorized PCCP.

In general, device labeling should include an adequate description of the device and its PCCP to ensure appropriate use of the device. Device labeling must also comply with applicable statutes and regulations, which includes adequate directions for use. FDA may also require that a device with an authorized PCCP include labeling required for safe and effective use of the device as the device changes in accordance with the PCCP. As it pertains to the PCCP, we recommend that the labeling include a statement that the device has an authorized PCCP.

Additionally, as modifications are implemented consistent with the authorized PCCP, we recommend that labeling related to the PCCP be updated to include a description of the implemented modifications, including a summary of current device performance, a description of the relevant data, which includes training, tuning, or testing data, associated inputs or outputs, validation requirements, and related evidence. A description of how the modifications were implemented and a description of how users will be informed of implemented modifications such as updated instructions for use or a version history.

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Ayobami Adebowale: Similar to the content in the labeling about the device's authorized PCCP, we also provided a summary of information that should be included in the public decision summary for the device, such as in a 510(k) summary or a PMA summary of safety and effectiveness document, or SSED.

Again, this information should be included in sufficient detail to provide transparency to users about the device and its specifications. Specifically, the public facing document include information about the PCCP as appropriate, including a summary of the plan modification, testing methods, validation activities, and performance requirements to be met in order for modifications to be implemented, and means by which users will be informed of device modifications implemented in accordance with the authorized PCCP.

As you can see, we've made revisions to provide a bit more detail on the information regarding the PCCP that should be included in the labeling and public decision summary.

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Ayobami Adebowale: We have also added a new concept to the final guidance to provide some clarity regarding version control of a PCCP. In general, we recommend that manufacturers submit a copy of the proposed PCCP with a title and version number.

FDA expects that reviews for devices with PCCPs will be very interactive. As such, FDA and the manufacturer should work together to revise the PCCP consistent with our existing processes. If the proposed PCCP is revised before the device and PCCP are authorized, that final, revised version of the PCCP should be submitted as a clean copy with a title and the current version number.

As we've mentioned before, the PCCP is part of the marketing authorization of the device. And to that end, the PCCP will be referenced in the device's letter of authorization and will include that title and version number to provide transparency on what has been authorized. If the proposed PCCP is not successfully revised because, for example, deficiencies with the PCCP remain unresolved, FDA may authorize the device upon withdrawal of the PCCP.

A manufacturer should only have one version of an authorized PCCP for their device. However, that authorized PCCP can evolve over time through future marketing submissions where a new version of that PCCP can be authorized. This concept ties to version control as well, as there should only be one version of the PCCP under review with the device at any given time to help with version control of the PCCP for both manufacturers and FDA.

Now that I've covered the proposed recommendations for the components of the PCCP and where to include the PCCP in your marketing submission for an AI-DSF, I'll pass it to MiRa to continue with the detailed recommendations for the PCCP. MiRa?

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Dr. MiRa Jacobs: Thanks, Bami. Okay, so now let's revisit each of the components of a PCCP again and reaffirm and highlight some of the specific recommendations provided in the final guidance.

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Dr. MiRa Jacobs: We'll start back at the beginning with the description of modifications, which, as we mentioned earlier, defines what a manufacturer intends an AI-DSF to become over time.

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Dr. MiRa Jacobs: As you'll remember from earlier in this webinar, a PCCP is intended to include the specific changes to an AI-DSF that would otherwise require a new marketing submission. The goal of the description of modification section is to identify those specific planned modifications to the AI-DSF.

The description of modifications should also present each modification at a level of detail that permits understanding of the specific planned changes to the AI-DSF. This includes stating whether the modifications are to be implemented manually or automatically, as well as whether the modifications are to be implemented globally or locally.

In the final guidance, FDA specifically clarified recommendations for manually or automatically implemented modifications. Importantly, FDA does recognize that automatic modifications have an additional degree of complexity. But as with all devices, we'll consider the benefit risk profile of the specific AI-DSF, as well as the specific modifications being proposed. To help facilitate FDA's review, it may be helpful to clearly establish boundaries or guardrails that define the range of automatic updates.

As a general tip, we recommend that a PCCP really only include a limited number of modifications that are specific and can be verified and validated to help ensure an efficient review.

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Dr. MiRa Jacobs: Alright. Now, let's briefly touch on the kinds of modifications that may be generally appropriate to include in a PCCP. In general, there are many factors to consider in determining if a modification is appropriate for inclusion. They should be modifications that maintain or improve the device safety or effectiveness.

As noted on the prior slide, modifications included in a PCCP should be specific and should be able to be verified and validated. Finally, modifications must maintain the device within the device's intended use. Further, and in general, FDA does believe that modifications included in a PCCP should also maintain the device within the device's indications for use.

However, certain modifications to the indications for use, such as changes in the indications for use to specify use of a device with an additional compatible device or component may be appropriate to include in a PCCP. That said, FDA highly encourages manufacturers to first discuss modifications to the indications for use that they may be including in their proposed PCCP with the FDA through a Pre-Submission.

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Dr. MiRa Jacobs: Alright. So, while we just went over some broad considerations for the types of modifications that may be appropriate to include in a PCCP, which do apply for AI-DSFs, the final guidance also provides three recommended modification types that are appropriate to include in a PCCP for an AI-DSF in particular.

The first modification type includes modifications that are related to quantitative measures of AI-DSF performance specifications. For example, this could include specific improvements to analytical and clinical performance, resulting from retraining the AI model based on new data within the intended use population from the same type and range of input signal.

The second modification type includes modifications related to device inputs to and compatibility with the AI-DSF, including changes to data type specifications, such as new sources of the same input signal type, or limited modifications related to new types of inputs.

The third modification type includes certain modifications related to a device's use and performance, such as authorization of a device for a particular subpopulation within the originally indicated population based on retraining on a larger data set for that subpopulation that perhaps was not previously available.

In general, there are many modifications that may be appropriate to include in a PCCP for an AI-DSF, and this final guidance focuses on certain specific modifications for AI-DSFs. However, this final guidance is not intended to delineate a comprehensive list of modifications that FDA would consider reasonable to propose for an AI-DSF.

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Dr. MiRa Jacobs: Okay, now, let's move on to talk about the modification protocol, which, as a reminder, provides the how to support the what that is delineated in the description of modifications that we just discussed.

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Dr. MiRa Jacobs: In brief, the modification protocol section describes the methods that will be followed when developing, validating, and implementing the modifications in the PCCP.

This section should include the verification and validation activities, including predefined acceptance criteria that will support each modification to ensure the device remains safe and effective as changes are implemented. The modification protocol should also include information tailored explicitly to every proposed modification that was described in the description of modification section.

In general, we also recommend that the modification protocol include a description of how the methods in this section are similar to or different from the methods that were used elsewhere to support the marketing submission for your device.

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Dr. MiRa Jacobs: In a little more detail, for each modification included in the description of modification section of a PCCP, the modification protocol should address four different areas.

One, the relevant data management practices. Two, the retraining practices. Three, defining performance evaluation. And four, planned update procedures. As highlighted on this slide, the final guidance also includes additional specific recommendations for each of those four components for an AI-DSF specifically. These recommendations are available in Appendix A of the guidance, and they provide example considerations of the kinds of information to cover within these four different components of the protocol. These recommendations help to more functionally illustrate the role that the modification protocol is intended to provide in a PCCP for an AI-DSF and the level of specificity that we recommend when developing these plans as part of a marketing submission.

However, please note that Appendix A is meant to provide FDA's recommendations on some helpful questions for manufacturers to consider when developing their modification protocols, and that these questions are not exhaustive and are not intended to cover all possible details, risks, or considerations for all AI-enabled devices.

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Dr. MiRa Jacobs: Before we move on to talk about the last section of a PCCP, I do want to briefly talk about traceability in a proposed PCCP. Up to this point, we've discussed how each modification described in the PCCP should be clearly linked to activities laid out in the modification protocol. To help

demonstrate that each proposed change has been addressed completely within the modification protocol, we recommend that manufacturers include a traceability table in their PCCP.

A traceability table can clearly show which parts of the modification protocol are applicable to each modification included in the description of modifications. As shown on this slide and in the final guidance, a simple table can really help to clearly show the different methodologies applied to each proposed modification. Where they differ, and how they correspond to those four components of modification protocol that we just went over on the prior slide. Data management practices, retraining practices, performance evaluation, and update procedures.

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Dr. MiRa Jacobs: Okay, now, let's briefly discuss the last component of a PCCP, the impact assessment.

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Dr. MiRa Jacobs: The impact assessment section of a PCCP should include an assessment of the benefits and risks of implementing a PCCP for a device, as well as documentation of associated risk mitigations. An impact assessment should compare each version of the device with individually implemented modifications to the version of the device without any implemented modifications.

In addition to addressing the benefits and risks of each proposed modification, the impact assessment should also address how the activities in a modification protocol will continue to reasonably ensure that as each new change is implemented, the device remains as safe and effective as the unmodified version.

Lastly, the impact assessment should also include a discussion of how implementation of each modification impacts the implementation of another and the collective impact of implementing all modifications in the proposed PCCP.

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Dr. MiRa Jacobs: A final point to consider when developing the impact assessment section of a PCCP is that it should also discuss how the individual modifications impact not only the particular function being modified, but the overall functionality of the device. This could include how the PCCP impacts other device software functions or hardware in the device. Or, if the device is a combination product, this could also include how the PCCP impacts the biologic and/or drug constituent part, and similarly, the combination product as a whole.

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Dr. MiRa Jacobs: With that, I'd like to briefly go over an example to round out our discussion of PCCPs for AI-DSFs today. In Appendix B of the final guidance, we include example applications of a PCCP to help demonstrate how the policy and recommendations we've discussed throughout this webinar can be put into practice. Please note that the examples in the final guidance are intended to be illustrative, and they do not represent examples of complete PCCPs.

The example from the final guidance that I'll share today is for an optical imaging system co-packaged with an imaging drug. This product is a device-led combination product that includes an AI-DSF integrated into an imaging system co-packaged with an approved optical imaging drug. In this case, the AI-DSF analyzes images in real time and highlights potential cancerous lesions for further evaluation. For this example, the product was authorized with a PCCP.

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Dr. MiRa Jacobs: For this AI-DSF and PCCP, the manufacturer proposed a modification to improve the speed of lesion detection through retraining, which was authorized. Specifically, in this example, the

PCCP states that the speed of lesion detection can be improved, provided that the sensitivity and specificity do not fall below a pre-specified level.

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Dr. MiRa Jacobs: So, let's now explore two different potential modification scenarios after the hypothetical device and PCCP were authorized.

The first is the modification related to the device performance, as specified in the PCCP, and implemented in accordance with it. The second is an additional modification scenario, which could be a reasonable next step in the development of this device, but it isn't a modification that was specified in the PCCP. We'll go over each of these modification scenarios separately.

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Dr. MiRa Jacobs: In the first scenario, the manufacturer's AI-DSF was retrained using imaging data collected and analyzed in accordance with the modification protocol. And analytical validation demonstrated that the modified AI-DSF resulted in imaging processing speed improvements of 20%. The analytical performance of the modified imaging system was found to be statistically equivalent to the device's baseline performance, as specified in the modification protocol.

In this scenario, because the device modification was both specified in the PCCP and it was implemented in conformance with the PCCP, the device modification was implemented acceptably and would not require any marketing submission. The manufacturer should still ensure that they document the modification that was specified in their PCCP in accordance with their quality system.

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Dr. MiRa Jacobs: In the second scenario, the manufacturer would like to distribute a new version of the AI-DSF that will be used with a modified dosing regimen of the co-packaged imaging drug. However, this modification was not included in the PCCP, and it could significantly affect the safety or effectiveness of the device. Therefore, in this scenario, the manufacturer must submit a new marketing submission for the proposed modified device.

Further, consistent with the scope of this final guidance, it is important to remember that the recommendations do not apply to modifications to the drug or biologic constituent part of the device-led combination product.

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Dr. MiRa Jacobs: With that, we hope that today's webinar helped you understand the FDA's policy for PCCPs for AI-enabled devices. With this final guidance, we intended to first describe FDA's approach to PCCPs for AI-DSFs to support their iterative development and improvement over time. Second, to explain FDA's recommendations on information to include in a PCCP that is provided as part of a marketing submission for an AI-enabled device. And third, to explain FDA's recommendations regarding the types of modifications that may be included in a PCCP for an AI-DSF.

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Dr. MiRa Jacobs: If you're planning to pursue a PCCP for your AI-enabled device, we do strongly encourage you to engage with FDA early and often. Submitting a Pre-Submission to discuss your proposed PCCP can be an incredibly helpful way for you to obtain feedback on your proposed PCCP for your AI-enabled device, the proposed submission type for the device and PCCP, the specific proposed modifications you may wish to include in your PCCP, and in particular, if you plan to have automatically implemented modifications or local implementations of your AI-enabled device or propose modifications to a previously authorized PCCP.

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Dr. MiRa Jacobs: Throughout this presentation, we've provided several references to give additional context and clarity for the recommendations. In the final guidance, you can see them aggregated and linked here for your reference after the presentation.

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Dr. MiRa Jacobs: And lastly, we've also included the acronyms that were used during today's presentation for your later reference.

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Dr. MiRa Jacobs: With that, thank you so much for your time and attention, and I will now turn it back over to Kim to moderate the Q&A session.

CDR Kim Piermatteo: Thank you, Jessica, Bami, and MiRa for your presentations. As MiRa mentioned, we will now transition to our interactive question and answer segment. Joining our presenters for today, we have a few additional panelists.

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CDR Kim Piermatteo: That is Dr. Kathryn Drzewiecki, Team Lead in the Division of Digital Health Policy in CDRH's Digital Health Center of Excellence; Dr. Nicholas Petrick, Deputy Director for the Division of Imaging, Diagnostics and Software Reliability in CDRH's Office of Science and Engineering Laboratories; Dr. Amir Khan, Senior Staff Fellow on the Imaging Software Team within the Office of Radiological Health in CDRH's Office of Product Evaluation and Quality, or OPEQ; and Aneesh Deoras, Assistant Director for the Cardiac Ablation, Mapping, and Imaging Devices Team in the Office of Cardiovascular Devices in OPEQ as well. Thank you all for joining our panel today, and we look forward to our interactive discussion today.

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CDR Kim Piermatteo: Before we take our first live question, I would like to go over how we will manage this segment and a few reminders.

First, to ask a question, please select the Raise Hand icon, which should appear on the bottom of your Zoom screen. I'll announce your name and give you permission to talk. When prompted in Zoom, please select the blue button to unmute your line and then ask your question. When asking your question, please remember to limit yourself to asking one question only and try to keep it as short as possible.

And we appreciate that you may have a very specific question involving your device or scenario; however, we might not be able to answer such specific questions. Therefore, we'll try to frame a broader response based on what's described in the guidance.

After you ask your question, please lower your hand in Zoom and then if you have another question, please feel free to raise your hand again in Zoom to get back into the queue and I will call on you as time permits.

Before we take our first live question, I would like to go to our newest panelist and ask some previously received questions about this guidance. So, the first question I would like to direct to Kathryn. Kathryn, that question is, how does this final guidance on Predetermined Change Control Plans for AI-enabled Devices relate to the Predetermined Change Control Plans for Medical Devices draft guidance?

Dr. Kathryn Drzewiecki: Thanks for that question, Kim. As described throughout today's webinar, the marketing submission recommendations for a PCCP for AI-enabled device software functions final guidance describes a policy and recommendations for PCCP use for AI-enabled devices. Specifically, the

guidance provides recommendations on the information to include in a PCCP in a marketing submission for a device that includes one or more AI-enabled device software functions.

The guidance recommendations, such as the content of those PCCP components that we talked about today, are focused on providing further information and addressing questions specific to AI-enabled devices. This is a final guidance and is for implementation.

The Predetermined Change Control Plans for Medical Devices draft guidance proposes a policy and recommendations for PCCPs for any device type. In that draft guidance, the proposed policy and content recommendations for PCCPs are very similar to what we heard about today to this final guidance but are generalized to any device type. That draft guidance also proposes additional recommendations on how to determine whether a modification may be appropriate for inclusion in a PCCP for a device. Although that guidance is draft and is not for implementation, Section 515C of the FD&C Act is in effect and is self-executing, and therefore manufacturers may submit, and the FDA may approve or clear a PCCP for any device at this time.

In general, the guidances are consistent at a high level, but the marketing submission recommendations for a PCCP for AI-enabled device software functions guidance, the content of this webinar today, and where the questions and answer session should be focused, this guidance is final and focuses on recommendations specific to AI-enabled devices.

CDR Kim Piermatteo: Thanks, Kathryn. Okay, Nick, I'm going to come to you with another question. And Nick, that question is, does this guidance apply to devices that are continuously learning or adaptive?

Dr. Nicholas Petrick: Thanks for the question. In general, yes, this final guidance is applicable to AI-enabled device software functions that a manufacturer intends to modify over time. This includes AI-enabled device software functions for which modification to the AI model are implemented automatically, and these are known as continuously learning or adaptive AI.

We strongly encourage manufacturers to consider discussing a proposed PCCP containing modifications that are implemented automatically with FDA through the Pre-Submission process prior to submitting a marketing submission to receive feedback on those modifications and the proposed PCCP.

CDR Kim Piermatteo: Thanks, Nick. Okay, Amir. Amir, the question I have for you is does this guidance apply to modifications to generative AI-enabled devices? If yes, does FDA have any recommendations when submitting a PCCP for a generative AI-enabled device, for example, any specific validation data recommendations?

Dr. Amir Khan: Thank you for the question. So, this final guidance is applicable to AI-enabled device software functions that manufacturers intend to modify over time, as Nick said, including AI models that are logged to continuously learning, but also to various implementations of AI models such as non-generative AI or generative AI.

While this final guidance is applicable to AI-enabled devices, generally, it does not have a specific recommendations for different AI implementations, such as generative AI. So, in general, as was said elsewhere, FDA strongly encourages manufacturers to consider discussing a proposed PCCP for a generative AI-enabled device with FDA through a Pre-Submission prior to submitting a marketing submission to receive feedback on the proposed PCCP.

CDR Kim Piermatteo: Thanks, Amir. Alright, so before we take our first live question, Aneesh, I wanted to come to you with another question. And then we'll take our first live question. So, Aneesh, the question is I want to use a device with an authorized PCCP as a predicate for my device. What version of that device do I use as the predicate device and where do I find the predicate information?

Aneesh Deoras: Yeah. Thanks, Kim. Yeah, so for devices subject to 510(k) requirements and making a determination of substantial equivalence where the predicate device was authorized with the PCCP, the subject device must be compared to the version of the predicate device cleared or approved prior to the

changes made under the PCCP. However, once a 510(k) for a device that includes modifications implemented consistent with the authorized PCCP has been cleared, that device can now serve as an eligible predicate device.

FDA identifies all devices cleared through the 510(k) process in the publicly available FDA 510(k) database. This online database is updated monthly by the FDA and includes basic administrative information that industry can use to begin identifying valid predicate devices. Nearly all modern legally marketed devices also have publicly available 510(k) summaries, indications for use documents, and substantial equivalence letters. Users will generally find information about the version of the device and the PCCP that was authorized by FDA in the device's letter of authorization, including the PCCP title and version number.

CDR Kim Piermatteo: Thanks, Aneesh. Okay, we're going to take our first live question. Our first live question is coming from James. James, I have unmuted your line. Please unmute yourself and ask your question.

James Domine: Thanks very much, Kim. And hey, thank you to everybody who presented today and put this together. It is hugely appreciated by, I'm sure, all of my industry peers and myself. It's super exciting to see what we can do with PCCPs.

My question goes to the pathways that came out in this final guidance. The final guidance was very specific on pathways that could be included for submission of a PCCP. And one of the things it did narrow down on was it did exclude a special 510(k) for initial submission of a PCCP. That wasn't in the previous guidance, and it's really not addressed in section 515C of the FD&C Act. So just really a question. I'd love to understand a little more around the rationale around that and whether it's just because PCCPs are so new and/or whether there's any chance that will change in future. Thank you very much for consideration.

CDR Kim Piermatteo: Thank you, James, for that question. I think I'd like to go to Jessica first. Jessica, do you want to provide a response? And then if any of the other panelists want to chime in, please feel free.

Jessica Paulsen: Sure. Happy to. And James, thank you so much for the question and your support of PCCPs. We're also excited to be here and chat with you all.

So, regarding Special 510(k)s, I think what we've outlined in the guidance is that we do see this as a pathway for modifying previously authorized PCCPs. That seems like a pretty good fit. Obviously, the modification would matter. The specifics would matter. But in general, I think establishing a PCCP for a device may be difficult through a Special 510(k) just given the information needed to review, but again, the specifics matter for a given PCCP. But I do think there's really clear value in leveraging the Special 510(k) pathway for modifying a previously authorized PCCP, which we envision being something that sponsors may wish to do over time. I hope that helps. And feel free, others, to chime in and add.

CDR Kim Piermatteo: Thanks, Jessica. Thanks, James. Anyone else want to add on? We'll just go ahead and take our next live question. Okay. Thanks again, James.

Alright. Our next live question is coming from Cesar. Cesar, I have unmuted your line. Please unmute yourself and ask your question.

Cesar: Hi, everyone. Can everyone hear me?

CDR Kim Piermatteo: Yes, we can.

Cesar: Okay, my question is this. Imagine I already have a cleared AI-DSF device without a PCCP. But now, as part of company strategy, I want to add a PCCP to that already cleared device. Do I have to make another 510(k) submission?

CDR Kim Piermatteo: Thank you, Cesar, for that question, Kathryn, would you like to provide a response?

Dr. Kathryn Drzewiecki: Yeah, sure, Kim. Cesar, that's a great question. It's in the guidance we've described in section 5B that it would be appropriate to establish a PCCP for a device that's not yet on the market, and you want to have a PCCP or for a device that is on the market and that you want to add a PCCP, you would need to submit a 510(k). It's likely because PCCPs are containing modifications that would otherwise require a marketing submission that you are going to have to come back in and submit a 510(k) for that device.

CDR Kim Piermatteo: Thanks, Kathryn. Thank you, Cesar, for your question.

Cesar: Yeah, thanks.

CDR Kim Piermatteo: Okay. Our next question is coming from Erin. Erin, I have unmuted your line. Please unmute yourself and ask your question.

Erin Odor: Hi. Thanks so much for this presentation. My question is about the applicability of part 812 to modification protocol activities when those activities involve human subjects. Specifically, does FDA consider protocol modification, testing, or validation activities that adhere to an authorized PCCP to be an investigation conducted in accordance with the indications in the labeling the FDA reviewed in the original marketing submission? In other words, would clinical investigations conducted consistent with the device's authorized PCCP be exempt from the IDE requirements?

CDR Kim Piermatteo: Thank you, Erin, for that question. I'm not sure if any of the panelists want to chime in for this one?

Aneesh Deoras: Yeah.

CDR Kim Piermatteo: Oh, sure.

Aneesh Deoras: Hey, this is Aneesh on the line. Thanks so much for the question. It's a really good question because it portrays to, how do we actually implement these PCCPs. It really is going to depend on the device and what kinds of data you need to collect in order to make this happen.

There are a lot of cases where investigations are considered non-significant risk or even just basic science, and so they wouldn't need an IDE in that kind of case. You'd still have to work with IRBs depending on the site you're working at. So, it's going to be case specific, whether or not IDE regulations would apply. I think, ideally, though, the case would be that you wouldn't need an IDE to implement something within a PCCP. It's really something, you're going to have to talk with your individual review team to understand how best to handle that and how to move forward.

Erin Odor: Okay, I'm actually from an IRB. So, I'm asking from that perspective of whether or not we should consider these NSR or IDE exempt. But it sounds like the answer is, it will depend, as it often does.

Aneesh Deoras: It will depend. Yeah. I think it's probably likely that most will be NSR, because it would be really difficult to have IDEs for every PCCP change. And probably that kind of change would be so significant that it really wouldn't be eligible for a PCCP. But I think it's a great question and really appreciate your perspective there.

Erin Odor: Great. Thank you.

CDR Kim Piermatteo: Thanks, Aneesh. And thanks, Erin, for your question. Our next question is coming from Brian. Brian, I have unmuted your line. Please unmute yourself and ask your question.

Brian, are you able to unmute your line in Zoom?

Brian Schlossberg: Sorry about that. Can you hear me now?

CDR Kim Piermatteo: Yes, we can.

Brian Schlossberg: Okay, so my question is, is the PCCP guidance applicable for approved devices that already contain software algorithms that don't incorporate AI to include a plan for using AI methods to retrain and improve their performance?

CDR Kim Piermatteo: Thank you for that question, Brian. I'd like to turn it over to MiRa. MiRa, would you like to provide a response? And then if anyone else wants to add on, please feel free.

Dr. MiRa Jacobs: Sure, happy to. So, I mean, I hate to start with an it depends answer here, but I think that it's fitting. So certainly, the recommendations in this guidance could be applied in that case. And PCCPs can be used broadly for any device. But I think that that particular proposal would depend a lot on your specific device and exactly what the scope of the modifications you were intending to bring forward were. So that would certainly be a case that we'd definitely recommend discussing in advance with us via Pre-Submission. But I do think that that's a reasonable use case to look at this guidance and look at some of the recommendations there on how to scope the content you provide in your proposed PCCP.

Brian Schlossberg: Awesome. Thanks.

CDR Kim Piermatteo: Thank you, Brian, for your question. And thank you, MiRa, for your response.

Dr. Nicholas Petrick: I could just add a little bit more to that as well. I think that approach is going to be a little bit problematic in the sense that the studies that you utilize for the AI may be very different than you used in the original software device.

So again, it certainly depends on what those original software functionality was, but having a completely different set of studies, designs, and characteristics, it's going to be a little bit more difficult to implement within the PCCP without having a device that maybe has some of those data and requirements done. Now, maybe that might come in a predicate device already, but just something to think about as you're contemplating that pathway.

CDR Kim Piermatteo: Thanks, Nick, for those additional comments. And thanks again, Brian. Alright, next question we have is coming from Nilam I have unmuted your line. Please unmute yourself and ask your question.

Nilam: Hello. Can you hear me?

CDR Kim Piermatteo: Yes, we can.

Nilam: Perfect. Okay, my name is Nilam, just to clarify. So, my question is if submitting a traditional 510(k) using eSTAR and you want to include a PCCP, where or how should it be submitted along with the eSTAR?

CDR Kim Piermatteo: Thank you for that question, Nilam. I'm going to turn it over to Jessica.

Jessica Paulsen: Yeah. Thanks, Kim. So, in eSTAR, there is a specific attribute that you can check in the device description area that allows you to indicate when you have a PCCP in the submission that you're proposing and providing to FDA. And then when you click that attribute PCCP, there will be an option to add attachments.

And there's some help text there describing the attachments that we expect, as we've described in this webinar today. It will suggest that you include the description of the modifications, the modification protocol, and the impact assessment, and you would just attach them right there.

Nilam: Okay, thank you.

Jessica Paulsen: Yeah, no problem.

Nilam: I see it in the eSTAR now. Okay. Thank you so much.

Jessica Paulsen: Thank you.

CDR Kim Piermatteo: Great question. And thanks, Jessica. And thanks, Nilam. Our next question is coming from Sheila. Sheila, I have unmuted your line. Please unmute yourself and ask your question.

Sheila Walcoff: Hi, thank you all for doing the webinar. It's really helpful. I wanted to know a little bit more about your rationale for using a later version number, it sounds like, that you're suggesting using a later version number than version number one for the first authorized PCCP with the submission. Is that correct?

CDR Kim Piermatteo: Thanks, Sheila. I'm going to turn it over to any of our panelists. I think, if somebody needs clarification on her question, please feel free.

Jessica Paulsen: Yeah, this is Jessica. I might need a little bit of clarification.

Sheila Walcoff: Sure.

Jessica Paulsen: When you mentioned a later version number, is this about what Aneesh was commenting on when thinking about predicates?

Sheila Walcoff: No, I was thinking, so when you have your submission with a PCCP, and we've already done one of these, but it sounds like if you have rounds back and forth with the review team, so it would presumably be version 1. Then if it's changed, version 2, version 3, and then you want a clean version submitted with the then current version number, which could be, for example, nine. And so, I thought I heard earlier in the webinar that you would then call the first the authorized PCCP that is included with the authorization or the clearance or approval version 9 versus as opposed to version 1. So, you're looking at all the different draft versions. And then which version number will the authorized PCCP become?

Dr. Kathryn Drzewiecki: Thanks. This is Kathryn. I'll just start. And if others want to chime in, please do. So maybe just to clarify, I don't think we're recommending necessarily a specific version number or that you follow a specific system. In general, we're recommending that you include a title for your PCCP and that you have a version number associated with it and have whatever version number system you'd like, whether it's like a 1.1 or a 1.2, or you go from 1 to 2.0, whatever might work for your company and your quality system.

And we would just like it so that if there are revisions, as you are working with FDA on your PCCP, that you track those revisions and that we be made aware if there are changes, if you're responding to, for example, deficiencies or something of that nature, that you update your version number as you send us back a revised version or something like that, just so we're all clear on the version of the PCCP that we're looking at. And then ultimately what was authorized. But we don't have a specific recommendation for exactly how you go about doing that.

Shelia Walcoff: Right. I guess my question is, if you go back and forth with, and this happened, back and forth with different edits within the review team, as part of the review, and then you submit your clean final that everyone has agreed on between the sponsor and the review team and that maybe took a number of rounds. And you're then identifying that in your decision summary as version, whatever it is, beyond version 1, I guess I'm wondering what's the rationale for not just calling, when it becomes the authorized version, the first version for then traceability from there. I mean, you're really not implementing it in your discussion back and forth with the review team.

Dr. MiRa Jacobs: Hi, this is MiRa. I can add a little there. So, part of this is just ensuring that both the sponsor and FDA is on the exact same page on exactly which version, or we'll say, like, which revision of the first version of your authorized PCCP is. So, there are probably a number of ways of doing this.

If, from an internal tracking perspective, your company would prefer not to iterate up in version number and does not want to use a 1.01 system or something like this in your interactions with FDA, I think ensuring that a version that gets back to FDA is very clearly marked as like, hey, this is final or is otherwise titled in a way that makes it very clear exactly what we are agreeing on as being part of the authorization. That is fine.

So, we're not providing a specific recommendation that you need to follow a versioning system, and you may find that certain review teams may have a preference on how to keep track of it, but it's really just about traceability within a submission, which, as you've noted, there may be multiple rounds of going back and forth and talking about it. It's not really about implementing the particular document itself at that time. Does that?

Shelia Walcoff: Okay, yeah, that's really helpful, because the reason is, if you're going to have that version and traceability visible in your subsequent labeling, then I think it could become confusing to those that are not privy to the discussions that are happening within the review team. That if you have an authorized version and you've done that type of numbering, when it becomes authorized, as a titled version, as I used the example before, 9, from a perspective of when that device is authorized at the very beginning, it's sort of starting at version 9, which could be confusing later on when actual changes are made and you are updating that as those are made in your whatever versioning system you use. So that's why I asked.

CDR Kim Piermatteo: Great. Thank you, Sheila, for that discussion. Yep. Thank you, MiRa. Kathryn and Jessica, thank you. Okay, I think we have time for a few more questions. We'll try to get through today. The next question is coming from Sakina. Sakina, I have unmuted your line. Please unmute yourself and ask your question.

Sakina Mota: Hi. Thank you so much. So, this is similar to Cesar's question previously. So PCCP is relatively still new. And our 510(k) was cleared a while ago. But that does not include a PCCP. So, does that mean that we are not eligible to directly do a PCCP and would need a new 510(k)?

CDR Kim Piermatteo: Thank you Sakina for that question. I think I'd like to turn it over to MiRa first. MiRa, did you want to take a first response?

Dr. MiRa Jacobs: Sure. Happy to start. So, there's not a timing for eligibility in terms of if you'd like to introduce a PCCP for a device, other than it needs to come in as part of a marketing submission. So, if you already have a marketed device and you would like to introduce a PCCP for that device, as I think we covered a little bit in a prior question because of the nature of the changes you would be proposing within that PCCP, it would likely require a new marketing submission.

But just because the device has been on the market previously without a PCCP and you would like to introduce one now does not mean there's some sort of threshold or timing for which devices can or can't propose a PCCP in an appropriate marketing submission.

Sakina Mota: Understood. So, what I'm taking away is that it will still need a new marketing submission so that at least a PCCP can be introduced for future purposes?

Dr. MiRa Jacobs: Yes. You came across a little bit quiet, but if I understood you correctly, I think you heard me correctly, which was that you will need to submit a new marketing submission that includes the device that you would like to introduce a PCCP for, as well as the PCCP that you are proposing in that new submission and then through that clearance process, you can have an authorized PCCP with that device.

Sakina Mota: Perfect. Thank you so much.

CDR Kim Piermatteo: Thank you, Sakina. And thank you, MiRa for your response. We are at time, so unfortunately we're not going to be able to take any more live questions. But we do appreciate all of your

participation today. And I would like to thank all of our presenters and panelists for preparing and sharing the information about this final guidance for today's webinar as well.

So, at this time, I'm going to go ahead and turn it back over to MiRa to provide some final thoughts for today. MiRa?

Dr. MiRa Jacobs: Thanks, Kim. Thank you for doing a wonderful job moderating our session and echoed your thanks to all the participants today. Thank you all for joining. We really hope that you learned more about PCCPs for AI-enabled devices through this webinar today, including the recommended content for a PCCP in your future marketing submissions.

We're really excited to see the interest in PCCPs for these devices, and we look forward to engaging with all of you on your proposed PCCPs in the future. At the FDA, we really see this as a way to facilitate iterative improvements to AI-enabled devices in a least burdensome manner. So, with that, I will say thank you all for your time and your thoughtful questions today.

And I will take this as a last opportunity to emphasize that once again, if you are thinking about proposing a PCCP for your AI-enabled device, we really do hope you will consider reaching out to us early via a Pre-Submission. We are more than happy to discuss all of your great ideas and plans in that forum. And we look forward to hearing from you. So back over to you, Kim.

CDR Kim Piermatteo: Thanks, MiRa.

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CDR Kim Piermatteo: So, I would like to remind everybody, a recording of today's webinar and a transcript will be posted in the next few weeks to the Events page for this webinar, as well as to CDRH Learn under the section titled Specialty Technical Topics and the subsection titled Digital Health.

A screenshot of where you can find these materials in CDRH learn has been provided on this slide. If you have additional questions about today's webinar, feel free to reach out to us in DICE at DICE@fda.hhs.gov. And then we hope you're also able to join us for a future CDRH webinar and a listing of all of our upcoming CDRH events, including future webinars, is available via the link provided on the bottom of this slide at www.fda.gov/CDRHevents.

Thank you all again for joining us. This concludes today's CDRH webinar.

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