Qualification of Medical Device Development Tools
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Moderator: CDR Kim Piermatteo

CDR Kim Piermatteo: Hello and welcome to today's CDRH webinar. Thank you all for joining us. This is Commander Kim Piermatteo of the United States Public Health Service and I serve as the Education Program Administrator in the Division of Industry and Consumer Education in CDRH's Office of Communication and Education and I'll be your moderator for today's webinar.

Our topic today is the Medical Device Development Tools program, or MDDT program, and the associated final guidance titled, Qualification of Medical Device Development Tools, which was issued on July 17, 2023.

The MDDT program is intended to facilitate device development, timely evaluation of medical devices, and promote innovation by providing a more efficient and predictable means for collecting the necessary information to support regulatory submissions and associated decision making.

We are holding this webinar to discuss and answer your questions about the MDDT program.

Before we begin, I would like to provide two quick reminders. One, please make sure you've joined us via the Zoom app and not through a web browser to avoid any technical issues. And two, the intended audience for this webinar is industry. Members of media are encouraged to consult with FDA's Office of Media Affairs for any questions they may have.

It's my pleasure now to introduce you to our presenter for today's webinar, Jessica Mavadia-Shukla, Director of the MDDT program within the Division of All Hazards Response, Science, and Strategic Partnerships, and CDRH's Office of Strategic Partnerships and Technology Innovation.

We'll begin with a presentation from Jessica and then field your questions about today's topic. Thank you all again for joining us. I'd now like to turn it over to Jessica to start today's presentation.

Jessica Mavadia-Shukla: Good afternoon and thank you for the introduction. As described today, I will be presenting on CDRH's updated guidance on the qualification of medical device development tools. CDRH is committed to advancing innovations in regulatory science through qualification of medical device development tools which are needed to evaluate the safety, effectiveness, and performance of the products that we regulate.

This updated guidance describes the streamlined decision framework and processes for voluntary qualification of MDDTs. Please note that this guidance does not discuss the review of specific tools that are submitted in individual premarket regulatory submissions for use with a particular medical device, nor does it address the specific evidentiary or performance expectations of an individual MDDT submission.

In today's presentation, I will provide a brief introduction to the medical device development tools program, describe a medical device development tool, or MDDT, and the significance and benefits of MDDT qualification. I will then discuss the qualification decision framework, the phases of qualification,

as well as the regulatory considerations and recommendations. And finally, I'll end with how to submit an MDDT proposal to CDRH.

The MDDT Qualification Pathway is a voluntary program for qualifying tools for use in assessing the safety, effectiveness, or performance of medical devices subject to regulation by CDRH. CDRH believes the use of qualified tools will reduce regulatory burden when evaluating medical devices. It may also facilitate the development and timely evaluation of medical devices by providing a more efficient and predictable means for collecting the necessary information to support regulatory submissions and associated decision making.

For the purposes of this guidance, a submitter is any person, group, consortium, or organization, including the federal government, that takes responsibility for and initiates the MDDT qualification process using the procedures described in the guidance.

An MDDT is a method, material, or measurement used to assess the safety, effectiveness, or performance of a medical device. It is scientifically substantiated and can be qualified for use in device evaluation and to support regulatory decision making.

CDRH recognizes that broadly, there are three types of MDDTs which can be distinguished primarily from how the tool measures the relevant parameters. Non-clinical assessment models can be computational models, phantoms, or other models and methodologies that may inform device safety, effectiveness, or performance. Another category of tools is biomarker tests. For example, these are tools that measure molecular histologic, radiographic, or physiological characteristics. The last category is clinical outcome assessments, and these are tools that may assess symptoms and severity of a disease or an illness.

CDRH acknowledges that with the growing interest in digital health technologies, a tool may not strictly fall into any of these three examples. The overall categorization is only intended to serve as a guide or an example. Any tool that assesses the safety, effectiveness, or performance of a medical device may be submitted to the MDDT program for qualification.

Qualification is a conclusion based on CDRH review that, within the context of use or COU, an MDDT can be relied upon to have a specific interpretation and application in medical device development and regulatory review.

Once a tool is qualified, it can then be relied upon by CDRH reviewers without the need to reconfirm the suitability and utility of the MDDT when used within the qualified context of use in a regulatory submission. The intent of this voluntary program is to promote the development and use of tools to streamline device development and regulatory evaluation. Thus, we encourage developers to make their qualified MDDT publicly available. So let's now talk about why you should qualify your regulatory science tool.

There are many benefits to the qualification program, as you can see here. MDDT qualification can help to bridge the gap between research and development of medical devices and the delivery of high quality, safe, and effective devices to patients. Particularly beneficial is that a qualified MDDT can be used by multiple sponsors across multiple medical device development programs.

Furthermore, since CDRH intends to accept the results of a qualified MDDT without reconfirming the suitability or utility of the tool, this is likely to minimize uncertainty in the review process and increase overall efficiency of the review. Qualification also reduces individual resource expenditure through collaboration in the noncompetitive setting where multiple interested parties may work together and pool resources to expedite development, validation, and use of an MDDT.

When determining whether to qualify a proposed MDDT, CDRH will consider the following key factors, which I will describe further on the next couple of slides. Firstly, a description of the MDDT should be provided with the principle or concept of interest. Secondly, the proposed context of use should be adequately and appropriately defined. Third, the tool's overall regulatory utility should be clearly articulated.

For example, how does the tool's assessment help facilitate regulatory decision making? Is it used to assess safety, effectiveness, or some other important aspect of device performance? Fourth, the strength of evidence should demonstrate that the MDDT reliably and accurately measures what is intended. And finally, there should be an assessment of the advantages and limitations of using the MDDT to support a regulatory submission.

The context of use, or COU, is a key aspect of qualification. It describes the way the MDDT should be used, the purpose of the MDDT, and the conditions under which the MDDT is qualified. Once an MDDT is qualified, the COU should clearly describe the specific role of the MDDT in device development. For example, whether the tool is intended for use in design evaluation, animal testing, or early clinical studies. A complete COU should include the specific output or measure from the MDDT, the role of the MDDT, and the product area or areas in which the MDDT can be used.

Another key component of the decision framework is the strength of evidence. Submitters should explain how the strength of evidence for use of the MDDT is adequate to support the proposed COU. Evidence should include performance characteristics of the tool to describe how well the tool performs the measurement proposed in the COU.

The type of evidence needed will vary depending on the tool type and the COU. It may include, but is not limited to design verification, simulation results, bench, or animal performance data.

This evidence could also include clinical data or even human factors testing.

Finally, thorough a review of the evidence, an assessment of advantages and limitations should be made. Advantages highlight the impact of tool use in support of evaluating safety, effectiveness, or device performance. Limitations should identify conditions under which the tool should not be used or may not provide a meaningful assessment for regulatory decision making.

I'm now going to describe the MDDT qualification process. There are two phases in MDDT qualification. The first is the proposal phase. During this phase, the agency reviews a proposal from the submitter to determine suitability and to provide feedback on the overall qualification plan. If a proposal is suitable and the qualification plan is sound, the two will be accepted into the MDDT program.

The next phase is qualification phase. During this phase, the agency reviews the evidence provided based upon the agreed qualification plan to determine if it supports the proposed context of use. If so,

the tool will be qualified. If not, the agency may recommend changes to the COU or may determine not to qualify the tool. Please note the agency only intends to qualify tools where some high-level information about the existence of the tool and their utility can be made public.

The first step for anyone interested in qualifying an MDDT is to submit a proposal to us. However, interested submitters may always reach out to the program via the MDDT email inbox with questions or to discuss your tool prior to sending in a submission. In the next two slides, I'm going to discuss the key content to include in the proposal and qualification phases.

In the proposal phase submission, we expect to see the key information listed on this slide. It is important to ensure that you provide a thorough description of the tool. The information included in the description will depend on the type of tool, scientific principle, and how the output is achieved.

The next item is the proposed context of use statement. It is important to note that the context of use statement should be concise and include only key information that allows the tool user to quickly understand how the tool can be used to support assessments of safety, effectiveness, or device performance. Following the COU statement, the proposal should also include the performance criteria and qualification plan. The performance criteria are important to describe the overall performance characteristics of the tool.

Finally, the qualification plan should include what evidence the submitter intends to collect to support the tool, as well as how the evidence will be collected. It is important to point out that during the proposal phase, typically submissions would not include data to support qualification. Acceptance into the program is based on the overall regulatory utility of the tool. We do not expect the submitter to have sufficient data to support qualification at the time of the proposal.

After making a decision to accept the proposal into the program, we will also provide any necessary feedback or considerations that the submitter may need to address in order to proceed to the qualification phase. If the proposal is not accepted into the program, we also intend to provide the factors contributing to this decision to the submitter. Finally, we intend to make a proposal decision within approximately 90 days of receipt of a complete proposal phase submission.

Moving on to the qualification phase. In this slide, I've summarized the content to include in this package. A qualification package should include the full proposal, along with the tool evidence, which may include full test reports, a discussion of how the strength of evidence supports qualification, and an assessment of advantages and limitations of tool use.

CDRH will review the evidence to determine if the tool can be qualified for the specified context of use. We intend to qualify the MDDT if the tool is adequately described, the proposed COU is appropriately defined, the strength of evidence supports use of the MDDT within the proposed context of use, and the probable advantages of using a tool outweigh the probable limitations for that proposed context of use. Once we have determined whether or not to qualify a tool, we intend to notify the submitter in writing of the decision. Qualified tools will also be publicly announced.

There are some regulatory considerations to keep in mind. Some tools may meet the definition of a device in section 201(h) of the Federal Food, Drug, and Cosmetic Act depending on how they are intended to be used. If a tool is only for use in device development or evaluation and is not for use in

diagnosing or treating patients or study subjects, it is unlikely that it would meet the definition of a device and therefore may be suitable as an MDDT.

A tool that meets the definition of a device in its intended use will not be considered an MDDT. It is important to note that some MDDTs may have both device uses as well as non-device uses, and submitters should reach out to CDRH if there are any questions.

Qualification of an MDDT is different from clearance or approval, which is needed to support marketing authorization for a medical device. The MDDT qualification program is not meant to replace standards development and the recognition process, nor the FDA's issuance of device-specific guidance documents. FDA views the MDDT qualification program as a complementary program for evaluating and recognizing tools that are useful for medical device evaluation and to support regulatory decision making.

Once CDRH qualifies a tool, we intend to publicly disclose a summary of evidence and basis of qualification, or SEBQ. This document includes a brief description of the tool and its principle of operation, the qualified context of use statement, a general summary of evidence to support qualification and discussion of the strength of that evidence, a brief assessment of advantages and limitations of using the MDDT for its qualified context of use, and finally, information on how a device developer can contact the tool developer for access to the tool. If a tool submitter has questions about the content and detail in the SEBQ, please raise those issues with CDRH during the proposal phase.

We are interested in receiving MDDT proposals from all interested stakeholders. Tool developers can be device sponsors, research organizations, consortia, or academics. The MDDT process is voluntary and there are no fees associated with your submission. A brief outline of the contents to be included can be found online with more details in the MDDT guidance.

When submitting your MDDT proposal, please ensure you use the CDRH Premarket Review Submission Cover Sheet and clearly identify your submission as an MDDT in the cover letter to facilitate the correct login. MDDT proposals and qualification packages are now tracked with a universal tracking number, UTN, as opposed to the informational meeting Q-Submissions.

If you are interested in submitting an MDDT proposal to the program, please visit our MDDT web page for the instructions to submit an e-copy online or by mail. If you have any questions, please email the MDDT inbox at MDDT@fda.hhs.gov.

In summary, the MDDT program is CDRH's voluntary pathway to qualify regulatory science tools. MDDTs are intended to assess the safety, effectiveness, or performance of a medical device, and are not intended to replace standards development and recognition, or device-specific guidance documents. Finally, when a tool is qualified through the MDDT program, FDA will make public the summary of evidence and basis for qualification.

To conclude, we believe that through programs such as the MDDT program, we are modernizing the regulatory evaluation process and reducing the time and resources needed to develop and assess new medical products. The MDDT program strives to streamline and facilitate regulatory decision making, so we hope to see qualified MDDTs being used in support of regulatory submissions. I want to thank you

for your time and interest in the MDDT program. This concludes my presentation for today and I'm happy to take your questions.

CDR Kim Piermatteo: Thank you, Jessica, for that presentation. We will now transition to the interactive question and answer segment of today's webinar where our panel is available to answer your questions about today's topic. I'd like to introduce our additional panelists who will be joining Jessica in answering your questions.

First is Brittany Caldwell, Assistant Director of the Partnerships to Advance Innovation and Regulatory Science team within CDRH's Office of Strategic Partnerships, or OST, and Lisa Simone, Senior Health Scientist within the All-Hazards Readiness Response and Cybersecurity team within OST as well. Thank you all for joining us.

Before we begin, I'd like to go over how we will manage this segment. 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. Then, when prompted, please select the blue button to unmute your line and then ask your question. After you ask your question, please lower your hand. If you have another question, please raise your hand again to get back into the queue, and I'll call on you as time permits.

A few additional reminders as well. One, please remember to limit yourself to asking one question only and try to keep it as short as possible. Two, we appreciate that you may have very specific questions involving your device or scenario, but we ask that-- we may not be able to answer such specific questions, but we'll try to frame a broader response based on what's proposed in the guidance, as well as in the program. And lastly, this is your chance to better understand the MDDT program and this final guidance, so we ask you to try to frame your questions with this in mind.

Now as we wait to receive some of your questions, I'd like to welcome our newest panelists with some questions we have gotten about the MDDT program. For our first question, I'll be directing that to Brittany. Brittany, the question is, how does MDDT qualification benefit medical device sponsors?

Brittany Caldwell: Thank you for that question. Medical device sponsors can rely upon qualified MDDTs to support the regulatory submission and CDRH reviewers will accept the results from the tool without the need to reconfirm the suitability and utility of the tool as long as the tool is used according to the qualified context of use.

CDR Kim Piermatteo: Great. Thank you, Brittany. For our next question, I'll be directing that to Lisa. Lisa, the question is, is there a cost to submit to the MDDT program?

Lisa Simone: Thanks, Kim. The answer to that question is no. The MDDT program is voluntary and there are no fees associated with the MDDT submission.

CDR Kim Piermatteo: Great. Thank you, Lisa. Alright, our first live question is coming from Zdenko Grajcar. I have unmuted your line. Please unmute yourself and ask your question.

Zdenko Grajcar: Oh, hi. My question is, does the MDDT tool have to be a commercial product or will you accept the tool which was designed by academia and is manufactured in small quantities? Like in this case, it would be the measurement of the cerebrospinal fluctuations. So it's a sensor device, ultimately.

CDR Kim Piermatteo: OK. Thank you for that question. I'm going to turn it over to Jessica to provide a response.

Jessica Mavadia-Shukla: Hi, yes. The tool does not need to be fully commercialized. A tool from an academic center that is later developed and distributed however you choose would be welcome to the MDDT program. Thank you.

CDR Kim Piermatteo: Thank you, Jessica. Alright, our next question is coming from Dan. Dan, I have unmuted your line. Please unmute yourself and ask your question.

Dan Teodorescu: Hello, this is Dan Teodorescu calling from Alcon. My question is, do you foresee there being a database where these tools can be searched for by the industry, or is it something that you anticipate specific vendors, or specific research institutions to essentially list their own products as being qualified under this program?

CDR Kim Piermatteo: Thank you, Dan, for that question. Jessica, would you like to provide a response regarding whether or not there'll be a database?

Jessica Mavadia-Shukla: Yes. So we don't have a database per se. However, the list of qualified tools is on the MDDT website in a tabular format. And with that list of qualified tools is the summary of evidence and basis for qualification, which will include the contact information for the tool developer so that medical device sponsors or manufacturers can contact the tool developer to gain access to the tool.

CDR Kim Piermatteo: Great. Thanks, Dan for the question. Thank you, Jessica for the response. I'd now like to circle back to Brittany. I have a question I'd like to read for you to provide a response. Brittany, that question is, you mentioned digital health technologies. Are digital health technologies reviewed differently?

Brittany Caldwell: Thank you for the question. Digital health technologies that are used to support the safety, effectiveness, or performance of medical devices may be submitted to the MDDT program for qualification through the same pathway as other types of MDDTs. If you have questions around a potential MDDT, please contact the MDDT program through our email inbox at MDDT@fda.hhs.gov. Thank you.

CDR Kim Piermatteo: Thanks, Brittany. Alright, I'm going to go back to our live questions. Our next question is coming from Gerald. Gerald, I've unmuted your line. Please unmute yourself and ask your question.

Gerald, are you able to unmute your line?

Alright. Gerald, if you have a question, please circle back in the queue. Alright, next I'm going to call on Caitlin. Caitlin, I've unmuted your line. Please unmute yourself and ask your question.

Caitlin: Hi. Thank you. My question was regarding clinical data sets that are not-- that have been collected previously and then you're sort of reprocessing the data using updated algorithms, or updated software. And does that really fall under the category of MDDT, or would that fall into some other tool?

CDR Kim Piermatteo: Thank you, Caitlin. Jessica, would you like to provide a response?

Jessica Mavadia-Shukla: Yes. Hi, Caitlin, thank you for your question. Data sets that are going to be used as validation data sets to help support an assessment of safety, effectiveness or performance would be welcome to the MDDT program. However, if you do have any questions about the particulars, please feel free to email our inbox MDDT@fda.hhs.gov. Thank you.

Caitlin: Thanks.

CDR Kim Piermatteo: Thank you, Caitlin. Thanks, Jessica. Alright, our next question is coming from Bhaskar. I've unmuted your line. Please unmute yourself and ask your question.

Bhaskar: Thank you for the opportunity. So my question is if, as an industry manufacturer, we were to use the MDDT from one of the developers listed on your database, would there be any commercial aspects to it? As in would we have to pay them, or-- I just want to understand the commercial aspects of it.

Jessica Mavadia-Shukla: Hey, Bhaskar. Thank you for that question. Regarding how the tool is distributed, that's at the discretion of the tool owner. So that's something that you'd have to work out with them because there's different ways in which tools can be distributed.

But it is important to note that in the SEBQ, the MDDT number, or submission number would be listed. And we request that if you're using an MDDT to support your marketing application, you list that MDDT submission number in your CDRH premarket review cover sheet so that we can ensure we are looking at the data through the lens of a qualified tool. Thank you.

Bhaskar: Thank you.

CDR Kim Piermatteo: Thanks, Jessica. Thanks, Bhaskar. Alright, our next question is coming from Xue Feng. I've unmuted your line. Please unmute yourself and ask your question.

Xue Feng: Hi. Thank you so much. My question is that if there are two proposals that maybe have a similar context of use, we will maybe possibly qualify two tools, or you maybe tell one of the tool developers that we might already have one?

Jessica Mavadia-Shukla: Hi, Xue Feng. That's a great question. Thank you for asking. No, our program is open to tools that may have similar contexts of use. We want to be able to qualify as many tools as possible that will enable the device community to have options to support their marketing applications with assessments of safety, effectiveness or performance. So we would be able to take tools that have similar context of use statements. Thank you.

CDR Kim Piermatteo: Thanks, Jessica, for that response. Alright, our next question is coming from Shilpa. I've unmuted your line. Please unmute yourself and ask your question.

Shilpa: Thank you so much for this opportunity. Great presentation. My question is around knowing if FDA is going to publish their prioritized or specific areas of focus for developing these tools like what FDA does with their Experiential Learning program, they kind of mark up their interests and industry then acts on it. Is there any such guidance here?

Jessica Mavadia-Shukla: Hi, Shilpa. That's a great question. So I think that we are going to be looking into making known specific priority areas. However, you can identify certain areas of interest that CDRH has through the news that we put out from our strategic priorities for 2022 to 2025.

That's just one way in which we can make known our interest areas. But if there's any questions about tools that the Agency may be interested in, you are more than welcome to email us at MDDT@fda.hhs.gov. We would love to have the conversation. Thank you.

Shilpa: Awesome. Thank you.

CDR Kim Piermatteo: Thank you both. Alright, our next question is coming from Nathan. Nathan, I've unmuted your line. Please unmute yourself and ask your question.

Nathan Piland: Hi, there. I was curious if an organization was to use the MDDT program to qualify a tool and then later wanted to turn that tool into a device, is the MDDT data set that was generated in order to get qualification able to be reused for your device submission, or do those need to be separate complete activities?

Jessica Mavadia-Shukla: Hey, Nathan. That's another great question. So it's going to ultimately depend on what you're doing with your product. I think that if you have very similar intended use, you may be able to leverage the data.

But there's no guarantee that the data that's used to support an MDDT will be entirely sufficient. So that's a conversation that we can have as a team later on. But you most certainly can submit to both MDDT and the regulatory pathway at a later time point. Thank you.

CDR Kim Piermatteo: Thank you, Nathan, for that question. Alright, our next question is coming from Barry. Barry, I have unmuted your line. Please unmute yourself and ask your question.

Barry Smith: Yes. The developers of the MDDT tool, are they required to allow their tool to be used by others? Or if they choose to keep it proprietary and for their own internal, use is that allowed through the program?

Jessica Mavadia-Shukla: Hi, Barry. That's a great question. So we don't get into how the tools are distributed, but we will make known that the tool was qualified through our MDDT website. And so ultimately, the goal is that these tools are made available.

How, or in which way you choose to distribute the tool as a tool developer is completely up to you. However, if it's going to be completely proprietary and not open or available to other medical device manufacturers, that may be a conversation we have to have at a later time. Thank you.

CDR Kim Piermatteo: Thank you, Jessica, for that response. Thank you, Barry, for the question. Our next question is coming from Mike. Mike, I've unmuted your line. Please unmute yourself and ask your question.

Mike Dunbar: Yeah, this actually is kind of complementary to Barry's question, but for an MDDT developed by a commercial company, it seems like they'd want to keep that strategy confidential from their competitors. So other than having supporting evidence for their submission, why would they choose to have this tool published for others in industry to see?

Jessica Mavadia-Shukla: Hi, Mike. That's a great question. So the information that is made public about a qualified tool is limited. It does not include proprietary information.

The tool developer will have the ownership of the tool and the way to distribute, sell, license however you wish to do so. However, going through the qualification process enables us to be able to really review the context of use statement and how the tool is intended to be used to support a marketing application, such that medical device manufacturers don't have to provide additional evidence or rationale on why the tool is being used, as long as it's used according to that qualified context of use. It also enables medical device manufacturers to quickly and more efficiently develop their devices, which is overall goal for us to be able to bring novel devices to patients first. Thank you.

CDR Kim Piermatteo: Thank you, Mike. Thank you, Jessica. Alright, I'm going to circle back to Brittany. Brittany, a question came in and asks, can you submit a tool to the MDDT program if you don't have all the data or evidence to support the proposed context of use?

Brittany Caldwell: Yes, absolutely. Tools can be submitted to the program without having collected all the evidence. During the proposal review process, the team will review the qualification plan, or plan to collect evidence and provide feedback on the adequacy of this plan via the MDDT proposal decision letter. If you haven't collected the data yet, this is a great time to obtain feedback before you do so. However, it's also OK to submit a tool to the program if you have collected the data or evidence to help support your context of use.

CDR Kim Piermatteo: Thank you, Brittany. Alright, the next person I'm calling on is George. George, I've unmuted your line. Please unmute yourself and ask your question.

George Allen Hides: Thanks so much for holding this. I appreciate the opportunity to ask. I may not be fully up to speed on this, but if the definition of an MDDT is a material, method, or measurement to assess the performance of a medical device and you develop an MDDT for a context of use that is a clinical outcome measure, can it be qualified for regulatory purpose to assess safety, effectiveness, and performance of a drug?

Jessica Mavadia-Shukla: Hi, George. That's a wonderful question. The MDDT program is CDRH's qualification pathway for device development tools. So having said that, a tool such as the one you're talking about, a clinical outcome, assessment, or measure for drug products would most likely be appropriate for the drug development tools program and not this one. Thank you for the question.

George Allen Hides: Thanks.

CDR Kim Piermatteo: Thanks, Jessica. Thanks, George. Alright, I am going to circle back to Jessica. We have a question. The current webinar only mentioned proposal and qualification phases when the previous guidance process included the pre-qualification and incubator phase. How does this impact the review process?

Jessica Mavadia-Shukla: Thanks, Kim. So with the current review process, we really intend to provide feedback to the submitters through the proposal and qualification decision letters, enabling our submitters to still receive feedback, however in a streamlined and shorter review time process. Thank you.

CDR Kim Piermatteo: Thanks, Jessica. And I have another one for you. So the question is, can we re-submit an MDDT submission for a different context of use?

Jessica Mavadia-Shukla: Yes, that's a great question. So an MDDT can be resubmitted for a different context of use, or to expand the original context of use with additional supportive evidence. Our process enables us to do that and update the SEBQ that's available online. Thank you.

CDR Kim Piermatteo: Thank you, Jessica. Alright, at this time, there are no more raised hands, so I want to make a call out to the audience. Please feel free to raise your hand, ask our panelists any questions you might have about the MDDT program, as well as the final guidance.

Jessica, though, I do have another question I'd like to ask, though, is what if a tool does not fit in any particular category?

Jessica Mavadia-Shukla: That's another great question. So the categorizations mentioned in this presentation are simply meant to be illustrative or as an example. We really want to receive tools to the program that are any type of assessment of safety, effectiveness, or performance to evaluate medical devices, and the categorization is more to help us identify how we should review the tool.

However, any tool is welcome to the program. And if you do have questions, please don't hesitate to email the MDDT inbox at MDDT@fda.hhs.gov. Thank you.

CDR Kim Piermatteo: Thanks, Jessica. Alright, Bhaskar. I'm coming back to you. You have another question. I've unmuted your line. Please unmute yourself and then ask your question.

Bhaskar: Thank you. I just want to check on the review timelines and is there any opportunity to expedite the timeline process?

Jessica Mavadia-Shukla: Hi, Bhaskar. That's a nice question. So we don't necessarily have a method to expedite. However, our internal goals, resource pending, are that we provide a review decision on proposal packages within 90 calendar days. So that's what we try to adhere to. And if there should be any delay, you would hear from me about the situation with the submission, or if there's other things going on at CDRH.

Bhaskar: Thank you.

CDR Kim Piermatteo: Thanks, Bhaskar. Thanks, Jessica. Alright, Jessica, I'm going to come back to you for another question. Do tools need to be qualified to be used to support device submissions?

Jessica Mavadia-Shukla: Thanks, Kim. So this is similar to another question we had earlier. Tools most certainly do not need to be qualified to be used in supporting a medical device submission. However, there is an added benefit of not having questions around the tool methodology, or appropriateness within the context of a regulatory submission when it is qualified. So there is that added benefit in addition to having your tool be made known through being public on the MDDT website and having more use within that medical device ecosystem. Thank you.

CDR Kim Piermatteo: Thanks, Jessica. Alright, next question is coming from Xue Feng again. Xue, I've unmuted your line. Please unmute yourself and ask your question.

Xue Feng: Yeah, thank you for the second opportunity to ask another question. So my question is that assuming we submit a tool and the tool is qualified, how much freedom do we have in terms of maybe making some changes to the tool? For example, I guess assuming we are developing some software tool and that's used for some performance evaluation, and the tool is qualified. Do we have to freeze the software for absolutely no changes, or can we still change maybe the non-essential part of the software?

Jessica Mavadia-Shukla: Hi, Xue Feng. Yes, that's a really good question. And when it comes to software-based tools, that is something that we describe in more detail and work out with the tool developer through the course of that MDDT review process.

There are certain types of changes which may be more permissible than others. However, we can talk about that and what the essential functions are. You can also refer to FDA's software guidances to see how we currently think about software and changes to software, as that might be a helpful indicator of how we might think about it.

Xue Feng: OK. Thank you.

CDR Kim Piermatteo: Thank you, both. I am going to come back to Bhaskar. Do you have another question, Bhaskar?

I apologize. Bhaskar, you had your hand raised. I'm not sure if that was again or if you didn't lower it from the last time.

Bhaskar: Sorry, there was an a technical glitch on my side. So I just wanted to check if there is any issue with the MDDT tool application, will there be any interactive reviews where we can discuss it over a teleconference call or something, or is it like the deficiency letter review process?

Jessica Mavadia-Shukla: Hi, Bhaskar. Yeah, that's a great question. So during those 90 calendar days of proposal review, we do have some opportunity for interactive review resource pending, and then there will be additional feedback within the context of the decision letter. However, if, at any point, you feel that you would like to have an additional discussion with the review team about that decision letter, you can reach out to me through the MDDT inbox and we can coordinate a way for you to receive additional feedback or discuss the feedback that you have received. Thank you.

Bhaskar: Great. Thank you.

CDR Kim Piermatteo: Thanks, Jessica. Thanks, Bhaskar. Alright, I'm going to come back to Shilpa. Shilpa, I've unmuted your line. Please unmute yourself and ask your question.

Shilpa: Thank you again. Knowing that MDDT is not a medical device, this is spurred by one of the lines that the reviewers mentioned about following draft guidance for software development, or existing guidance for software development and validation. Just curious if MDDT tool, after being approved, gets inspected. Do FDA inspections occur for any of these tools after it's released into the market?

Jessica Mavadia-Shukla: Hi, Shilpa. That's a good question. So MDDTs are not regulated in the way that our medical devices are, so I don't believe that there is an inspection for tools such as this. Thank you for that.

Shilpa: Thank you.

CDR Kim Piermatteo: Thank you both. Alright, I'm going to call on Zdenko Grajcar again. I've unmuted your line. Please unmute yourself and ask your question.

Zdenko Grajcar: Yeah, thanks. Thanks again. My question is, can MDDT tool be used as a diagnostic tool? I'll just explain. So let's just say we developed a tool which is able to assess the progression of the Alzheimer's disease, like where you are in Alzheimer's disease. Can this be used-- and is electronic device. Can this be used as an MDDT tool?

Jessica Mavadia-Shukla: Hi, Zdenko. Thank you for your question. So in terms of whether tools that fall under the medical device definition can be MDDTs or vice versa is very much dependent on the overall context of use and how the tool is being used. So if you do have questions or would like to discuss in more detail your specific scenario, feel free to email the MDDT inbox and we can discuss it more offline. Thank you.

Zdenko Grajcar: Yeah, thanks.

CDR Kim Piermatteo: Thank you both. Next, I'm going to call on Peymon Ghazi. I've unmuted your line. Please unmute yourself and ask your question.

Peymon Ghazi: Thank you very much. Are the slides going to be available and the recording?

CDR Kim Piermatteo: Yes. So following the webinar, we will post the presentation, which is the recording, as well as a transcript. So those will be available in about a week after the webinar.

Peymon Ghazi: Alright, thank you.

CDR Kim Piermatteo: We'll go over that on the next slide, too. We'll talk about CDRH Learn.

Alright. So I want to circle back with Lisa. I wanted to ask a question just to drive this point home for our stakeholders. The question we get often is, does the change in tracking MDDT packages impact the review process?

Lisa Simone: Hi, Kim. The shift of tracking MDDTs with a UTN number does not impact the review process. In fact, it helps us clearly identify the submission, and it does help facilitate the review. Thanks for that question.

CDR Kim Piermatteo: Yes, I think that's important. So thank you, Lisa. Alright, at this point, I would like to make one final call out for any questions from our audience today. If you have any questions, please raise your hand and I will call on you.

Alright, we have a question coming in from May. May, I've unmuted your line. Please unmute yourself and ask your question.

May Meng: Hello. I would like to ask for digital health technologies, will the cybersecurity issue needs to be addressed too in the application? Thank you.

Jessica Mavadia-Shukla: Hi, May. That's a great question. I think as far as cybersecurity is concerned, it does depend on the nature of the tool. You can most certainly visit and read through FDA's guidances on cybersecurity and software as they may give you some additional information and insight into how the Agency feels about these issues. Ultimately, we can talk about your specific submission and the needs of data and evidence within the context of the proposal. So you would receive that feedback through the review. Thank you.

CDR Kim Piermatteo: Thank you, May. Thank you, Jessica. Alright, our next question is coming from Beluh Mabasa. I've unmuted your line. Please unmute yourself and ask your question.

Beluh, are you able to unmute your line?

Beluh Mabasa: Yeah. Oh, sorry. Thank you. What is the benefits of the medical device to [INAUDIBLE]?

CDR Kim Piermatteo: I apologize, can you repeat that question? I had a hard time hearing you.

Beluh Mabasa: Yeah. My question is what is the benefits of the medical tool [INAUDIBLE]? The benefit, I mean. The benefit—

CDR Kim Piermatteo: What are the benefits of the tool?

Beluh Mabasa: Yes, especially if we want to develop our medical device related to-- when it is related to-- what's it mean-- if we use the artificial intelligence in our software or something like that.

CDR Kim Piermatteo: Jessica, do you need further clarification, or-- I think he's talking about the benefits of the tool.

Beluh Mabasa: Yes, yeah. The benefit of-- yeah.

Jessica Mavadia-Shukla: Yeah. So if I understand correctly, benefits of MDDTs that are qualified are to really highlight the predictability and efficiency of review. Especially in the case of AI, or machine learning-enabled devices, we would like to have more tools that are able to consistently and efficiently assess the safety, effectiveness, and performance of those types of devices.

By reviewing through the MDDT program, we can really take a look at the assessment methodology and determine if it would be appropriate for those types of devices, and then make it known to our medical device sponsors and our community through the MDDT website, whereby they would be able to rely on it to help ensure that their medical device regulatory submission review is streamlined and efficient, and there's no questions on how the safety, effectiveness, or performance assessment was done, or if that tool was adequate for that particular submission. Thank you.

Beluh Mabasa: OK. Thank you. Thank you very much. But I want to ask one question please. How about-- I mean, biocompatibility. Is it included-- must we prepare also the result test, I mean?

Jessica Mavadia-Shukla: So sorry, could you repeat yourself? Some of the words were a little difficult to understand.

Beluh Mabasa: Yeah. Maybe my question is a little bit stupid here. How about the biomedical-- I mean, biocompatibility, the result of biocompatibility. This include must be [INAUDIBLE].

Jessica Mavadia-Shukla: Yes. So the program is open to receiving tools for assessing biocompatibility of medical devices as well. That is definitely an area that the agency is interested in. Thank you for bringing it up.

Beluh Mabasa: OK. Thank you. Thank you very much for your answer.

CDR Kim Piermatteo: Thank you, Beluh. Thank you, Jessica. At this time, I'd like to make another call out. I see, Cee, I have unmuted your line. You have a question. Please unmute yourself and ask your question.

Cee: Hi, good morning. Can you hear me?

CDR Kim Piermatteo: Yes, we can.

Cee: OK. Just extending the question that was asked by the previous participant, if I go to the website, I see lots of links, Kansas City cardio questionnaire regarding cardiology, can you help me understand how do we use this tool?

Jessica Mavadia-Shukla: Hi. Sure, that's a great question. So some of the tools have different categorizations. The one that you're pointing out is a clinical outcome assessment.

So it would be used within the stated context of use that you can find when you click on the link to the summary of evidence and basis for qualification. It should be all the way on the right-hand side of the table. And you can always contact the tool developer or read more about the tool to see how you can use it. However, it is used to support clinical trials in the cardiology space.

Cee: OK. Alright, so basically go through that and try to leverage for our product.

Jessica Mavadia-Shukla: Yes, that's correct. And as you see all of the different summary of evidence and basis of qualification summaries, you would be able to see which tools would make sense for you to use in support of your marketing application. And where there are none, we would more than be happy to welcome these tools to come into the Agency. Thank you.

Cee: Makes sense. Thank you so much. Appreciate it.

CDR Kim Piermatteo: Thank you both. Alright, that will actually wrap up our live Q&A for today. I thank you all for an engaging question and answer segment. At this point, I would like to turn it back over to Jessica to provide her final thoughts for today.

Jessica Mavadia-Shukla: Thanks, Kim. So thank you everyone for attending this webinar and engaging with us through. And we are so excited to have shared the streamlined MDDT qualification program and process with you. We hope that we receive new MDDT proposals for your tools and definitely see more tools being used to support marketing applications.

Finally, I want to thank you again for your time and interest in the program, and please don't hesitate to email the MDDT inbox at MDDT@fda.hhs.gov if you have any follow up questions or inquiries. I would be happy to help address them. Thank you and have a wonderful day.

CDR Kim Piermatteo: Thank you, Jessica, for those final thoughts as well as your presentation. I'd also like to thank Brittany and Lisa for joining our panel and assisting and answering questions today.

As a reminder, printable slides of today's presentation are currently available on CDRH Learn at the link provided on this slide under the section titled Specialty Technical Topics and the recently created subsection titled Regulatory Science Tools. So take a look at that section.

A recording of today's webinar and transcript will be posted to CDRH Learn under the same section and subsection in the next few weeks. A screenshot of where you can find these webinar materials has been provided on this slide.

If you have any additional questions about today's webinar, feel free to reach out to us in DICE at DICE@fda.hhs.gov.

We hope you found today's webinar informative and hope you are able to join us for a future CDRH webinar. You can find a listing of upcoming webinars via the bottom link on this slide at www.fda.gov/CDRHWebinar.

This concludes today's webinar. And thank you all again for joining us.

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