

**FDA Webinar: CDRH Final Guidance: Qualification of Medical Device Development Tools**  
**Moderator: Irene Aihie**  
**August 24, 2017**  
**1:00 pm ET**

Coordinator: Welcome and thank you for standing by.

All participants will be in listen only mode until the question and answer session at the end of today's conference. At that time you may press Star 1 to ask a question.

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

I would now like to turn the call over to Irene Aihie. You may begin.

Irene Aihie: Hello and welcome to today's FDA webinar. I am Irene Aihie of CDRH's Office of Communication and Education.

On August 10, 2017 the FDA published the final guidance document entitled Qualifications of Medical Device Development Tools which includes the Pilot Program FDA launched in 2013 and finalizes the Medical Device Development Tools, MDDT Program.

The MDDT Program is voluntary and intended to reduce regulatory burden for tool developers and FDA reviewers with the qualification of tools that can aid in the development and evaluation of medical devices.

The purpose of today's webinar is to help clarify the agency's recommendations related to the content of the guidance document.

Today Hilda-Scharen Guivel, Director of the Medical Device Development Tools Program, will present an overview of the final guidance document and the MDDT Program. She is joined by members of the CDRH MDDT Working Group.

(Andrew Yeatts), one of the MDDT liaisons for the Office of Device Evaluation here in CDRH will present an overview of the MDDT process.

Following the presentation we will open the lines for your questions related to the information provided during the presentation.

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

Now I give you Hilda.

Hilda Scharen Guivel: Thank you. Good afternoon. As you know CDRH is committed to advancing regulatory science which provides the tools, standards and approaches needed to evaluate the safety, effectiveness, quality and performance of the products we regulate.

This guidance describes the framework and process for voluntary proposal and qualification of a Medical Device Development Tools, MDDT.

The outline for today's presentation will include an introduction to the MDDT Program, a summary of the benefits of MDDT qualification, a definition of what is an MDDT, a description of what qualification is as well as the qualification decision framework for qualification of a proposed MDDT followed by a description of the qualification process including the different phases and finally the regulatory considerations and additional recommendations.

The MDDT Program is a voluntary program for qualification of MDDTs for use in evaluating devices subject to regulation by CDRH.

CDRH believes this policy will reduce regulatory burden and 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 such as for example enrichment of a study population.

For the purpose of this guidance a submitter is a 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.

This guidance does not discuss the review of 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.

There are many benefits to the qualification program listed here. The MDDT Qualification Program provides a mechanism for leveraging advances in

regulatory science which 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. It 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.

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

CDRH recognizes three types of MDDTs which can be distinguished primarily by how the tool measures the relevant parameters, clinical outcome assessments, biomarker tests, nonclinical assessment models.

Qualification is a conclusion based on FDA review that within the Context of Use, 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 FDA staff reviewers without the need to reconfirm the suitability and utility of the MDDT when used within the qualified Context of Use in a CDRH 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.

When determining whether to qualify a proposed MDDT CDRH will consider the following key factors.

Is the MDDT adequately described?

Is the proposed Context of Use adequately and appropriately defined?

Would the scope and use of the tool have a broad public health impact?

Does the available scientific evidence demonstrate that the MDDT reliably and accurately measures what it intended, is scientifically plausible, and is reasonably likely to predict the outcome of interest?

Within the specified Context of Use and given the available strength of evidence, do the advantages outweigh potential disadvantages of making decisions based on the measurements obtained using the MDDT?

The Context of Use, 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 Context of Use defines the boundaries within which the available data adequately support use of the MDDT. The COU should describe the specific role of the MDDT in device development. Thus a complete COU should include: the tool or product area in which the MDDT is proposed to be qualified, the specific output or measure from the MDDT, the role of the MDDT in regulatory evaluation. For example for use in clinical studies, this includes the study population or disease characteristics, as well as the specific use: disease, diagnosis, patient selection so the endpoints.

And finally the phases of medical device development in which tool measurements can be used, for example for the pivotal clinical studies to support market applications.

Submitters should explain how the strength of evidence for use of the MDDT is adequate to support the proposed Context of Use. Evidence may include performance characteristics of the tool that would affect the usefulness of an MDDT such as tool validity and other performance characteristics to demonstrate that the tool provides accurate and precise measurements, predictive ability to describe the degree to which the tool measurement is related to the outcome of interest. Extent of prediction: the evidence should show the tool's ability to capture the aggregate effect on the true outcome of interest.

The type of evidence needed will vary depending on the tool type and Context of Use and may include but is not limited to: design verification, simulation results from computational models, bench or animal performance data, clinical data and human factors testing.

Qualification will depend on whether the probable advantages (outweigh) the probably disadvantages of making decisions based on using the MDDT in the course of developing and/or evaluating a medical device.

When assessing advantages and disadvantages of using a tool the following factors such as: type, magnitude and likelihood will be assessed as well as mitigation of disadvantages.

CDRH intends to place emphasis on regulatory, public health and/or clinical impact.

At this time I'm now going to turn it over to (Andrew) who will walk you through the qualification process.

(Andrew Yeatts): Thank you Hilda. I'm (Andrew Yeatts), the Office of Device Evaluation MDDT liaison.

I'm going to take a few minutes to go over the process in which we'll be qualifying MDDTs in CDRH.

The MDDT qualification process is divided into up to four phases. The first the proposal phase is a starting point for all MDDT submissions and is used to determine eligibility and prioritization into the MDDT Program.

The next two phases, the incubator and prequalification phases, are optional phases similar to the idea of a pre-submission in device submissions in which MDDT submitters may seek advice from us on their evidence gathering plan.

The final phase, the qualification phase, is the phase in which we will review the evidence to support qualification of a tool.

Since the MDDT Program is optional for both FDA and submitters the first step for all MDDT submissions is for the submitter to submit a proposal to us. The proposal is designed to be a relatively short document that is typically around 15 pages or less.

The desired content of a proposal are outlined in the guidance and include information including a description of the tool, the Context of Use, and a discussion of how this tool meets a public health need.

It is important to point out that this submission should not include data to support qualification. Acceptance into the program is not based on whether there's sufficient data at the time of the proposal but rather on the public health need for the tool, the benefits of the Context of Use and the availability of CDRH resources.

After making a decision to accept the proposal into the program we will recommend what phase we think will be most beneficial to the submitter. The recommendation of a suitable phase is not binding and only represents our best advice.

If the proposal is not accepted into the program we intend to provide the factors contributing to this decision to the submitter. We intend to make a proposal decision within approximately 60 days of receipt of a complete submission.

The first of the two optional phases is called the incubator phase. The goal of the incubator phase is for CDRH to work with submitters to foster the development of tools that have potential to significantly improve public health.

For example a tool that has high potential health impact but is not fully developed may be appropriate for the incubator phase. Once in the incubator phase submitters may submit packages to CDRH asking for feedback related to the tool development plan. CDRH intends to respond in writing to these questions and meet with the submitter if requested to aid in tool development.

The second of the two optional phases is the prequalification phase. In this phase submitters of fully developed tools may submit a plan to gather evidence to support tool qualification. This phase is similar to the – to a pre-



submission in a medical device submission. Once receiving a prequalification package we will conduct a review of the tool description, proposed Context of Use and evidence plan. And we will provide feedback addressing any potential studies or protocol modifications that could improve the evidence plan.

It is important to point out that we will not review data as part of an incubator or prequalification package. These stages are only to give feedback on the proposed plan to collect data. If we believe the evidence plan submitted appears adequate to support the proposed Context of Use we will recommend the submitter submit a qualification package.

The qualification phase is the final phase of the MDDT process. In this phase FDA will review all evidence and justification provided by the submitter to support qualification of the tool.

A qualification package should include a description of the tool and Context of Use, the complete evidence package, to support qualification including full test reports, a discussion of how the strength of evidence supports qualification and an assessment of the advantages and disadvantages of tool use.

The content of a qualification package are discussed in detail in Appendix 1 of the guidance. CDRH will review the contents to determine if the tool is qualified for the specified Context of Use. We intend to qualify the MDDT if the tool is adequately described, the proposed Context of Use 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 disadvantages for that proposed context.

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.

I will now turn it back over to Hilda who will discuss some of the remaining considerations discussed in the guidance.

Hilda Scharen Guivel: Thank you (Andrew). At this time I'm going to cover the regulatory considerations and related recommendations.

Some MDDTs may meet the definition of a device in Section 201(H) of the Federal Food Drug and Cosmetic Act. Whether an MDDT is a medical device will often depend on how it is intended to be used.

For example, if the MDDT product 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 it would be a device.

On the other hand if the MDDT is intended for use in diagnosing or treating or aiding in a diagnosis or treatment of subjects in a clinical study it would likely be a device.

A product intended for use in diagnosing or treating or aiding in the diagnosis or treatment of patients in clinical settings outside clinical studies would likely be a device but would not be an MDDT. Some MDDTs may have both device uses as well as non-device uses.

FDA qualification of an MDDT is different from FDA clearance or approval of a medical device. The type of evidence needed to support the MDDT

qualification is not the type of evidence that is needed to support marketing authorization for a medical device.

As described in Section IV. B FDA intends to evaluate tool validity, predictive ability and extent of prediction or capture when making qualification determinations.

The MDDT Qualification Program is not meant to replace the consensus standard development and recognition process nor 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.

As the voluntary MDDT Program is intended to promote the development and widespread use of tools to streamline device development and regulatory evaluation, these goals would best be served by making certain high level information about such tools public, so that device sponsors other than the tool developer would be aware of the existence and potential utility of qualified tools.

FDA intends to publicly disclose a Summary of Evidence and Basis of Qualification, SEBQ, if the FDA qualifies the tool. And this would include: a brief summary of the tool and its principal of operation, a qualified Context of Use, a general summary of evidence to support qualification and discussion of strength of that evidence, a brief assessment of advantages and disadvantages of using the MDDT for its qualified Context of Use and information on how a device developer can contact a tool developer to access the tool.

Any tool submitter with questions about the content and detail FDA intends to provide in the SEBQ should raise those with FDA during the proposal phase.

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. This promotes innovation, supports the manufacturer of high quality products and speeds the rate at which safe and effective medical technologies are made accessible to patients.

On behalf of the MDDT Working Group I want to thank you for your time and interest in this new exciting MDDT Program.

This concludes my presentation for today. And I think we're about ready to take your questions.

Coordinator: Thank you. And at this time to ask a question and questions will be taken only from the phone portion of today's conference, you may do so by pressing Star 1. Please unmute your phone and record your name clearly at the prompt. To withdraw your request, please press Star 2.

Once again at this time please press Star 1 to ask a question, once moment please for our first question.

Hilda Scharen Guivel: So one of the questions we have received is: How will the use of qualified MDDT speed the premarket review process?

(Andrew Yeatts): That's a good question, a common question we often get in ODE. And as part of the premarket review when we review a submission, we evaluate the data

presented by the manufacturer as well as the suitability of any tools or methodologies used in that application.

Use of a qualified MDDT in a medical device submission will potentially reduce the time it takes to evaluate that submission by removing the steps needed for repeated consideration of the suitability of scientific tools and methods used to develop and evaluate medical devices.

Irene Aihie: Operator we'll take our first question.

Coordinator: Thank you. First question from (Ron Shallingold), your line is open.

(Ron Shallingold): Okay. My question is does the MDDT Program apply to combination products? Can it be applied to combination products? And if so, is there some complication on which division would be reviewing the product (unintelligible)?

((Crosstalk))

(Andrew Yeatts): The MDDT – oh sorry. Thank you. And thank you for your question. This is (Andrew Yeatts). The MDDT Program is designed to qualify tools that can be used to support device submissions. I don't believe there'd be a particular limitation as to type of device led submissions they could be. It would of course have to be a device led combination product.

But I don't think there would be any restrictions beyond that. But in terms of the MDDT Program itself we're evaluating the tools not the products.

(Ron Shallingold): Thank you.

Coordinator: And we're showing no further questions but as a reminder Star 1 at this time to ask a question. One moment please.

(Caller): So some of the questions we received also is, is there a fee that's associated with this submission?

(Andrew Yeatts): So there aren't any fees. This is (Andrew Yeatts) again. There aren't any fees associated with the MDDT Program. So to submit a proposal there would be no fee associated.

I think another common question that we get is how you go about submitting an MDDT. We hope that people listening have found the program interesting and would hope some of you would be looking to submit.

Any individual group can contact us for consideration and to discuss the potential MDDT. A first step can be to email us at [mddt@fda.hhs.gov](mailto:mddt@fda.hhs.gov). And of course we also invite you to read our guidance and other materials that were submitted during this webinar.

Irene Aihie: We'll take our next question.

Coordinator: Thank you. (Jessica) your line is open.

(Jessica): Hi. Can you hear me?

Irene Aihie: Yes, we can hear you.

(Jessica): Okay. I was wondering. How do you look up the SEBQ of the qualified MDDTs?

Hilda Scharen Guivel: So this is information that we're going to have posted on our web site. At this time we don't have any qualified tools. But that information will be available on our web site.

(Jessica): Okay. And then once there is a qualified MDDT any other medical device companies can also use that tool. Correct.

Hilda Scharen Guivel: Just a second.

Ron Schuchard: This is Ron Schuchard, part of the Working Group. Once a tool is qualified and the SEBQ is public and you would find that you potentially might want to use that tool for your device development or evaluation, it would have information in the SEBQ on who you should contact; either the tool developer or who the tool developer designates as the contact person so that you would be able to then find out how to access the tool.

(Jessica): Okay thank you.

Coordinator: The next question is from (Dave Petrit). Your line is open.

(Dave Petrit): Yes hi. I just had a question on whether the MDDT, whether making that publicly available was optional or if that was required. And this was related to the previous question.

And although there is no MDDTs now can you provide some examples of, you know, what that type of tool would look like?

Ron Schuchard: So if I understood correctly you were – the first part of the question was to availability, the public availability.

(Dave Petrit): Is that optional or not, is that – is it required to make it publicly available or is that optional? And then the second part is and maybe if you could just provide examples.

Ron Schuchard: Right, but just wanted to clarify so the first part, it is stated in the guidance that it is expected that the tool will be able to be used not by just a single entity but it would be available to the public. We – the FDA, does not restrict usage nor do we guarantee usage. It is expected that it would be available to the public as the tool developer markets the tool.

(Dave Petrit): Okay great. Thanks. And then do you have some examples just to – in developing (unintelligible) as tools that would be effective in developing medical devices?

(Andrew Yeatts): So this is (Andrew Yeatts) from the Office of Device Evaluation. In ODE the type of tools we look at and that we would – in our device submission tools across the board particularly - specifically in the MDDT Program we're looking at clinical outcome assessments which would include something like a patient reported outcome measure.

As a center we've been looking for ways to incorporate more patient preference information and patient specific information in our regulatory decision making. So tools like patient reported outcome measures that can be qualified to accurately represent how patients might view the outcomes of a certain treatment by device are very interesting to us.

So that would be one example. We have some other people have worked on other types of tools that we see including the nonclinical assessment methods and our biomarker tests.



And maybe I'll turn it over to (Jay) who can talk about the nonclinical methods.

Jay Vaishnav: So hi. This is Jay Vaishnav representing the Office of Science and Engineering Laboratories. I'm also a member of the Working Group.

As Andrew mentioned, nonclinical assessment models are a type of MDDT. In fact, there's one that's completely online, available, and has open source development of the tool. It's called E-E-D-A-P, eeDAP, the Evaluation Environment for Digital and Analog Pathology.

So this is a tool used in the evaluation of whole slide imaging for digital pathology.

But more generally other sorts of tools that might be suitable for the program include any sort of modeling and simulation type tools that would help to develop a medical device.

(Dave Petrit): Great, thank you very much. I appreciate it.

Hilda Scharen Guivel: Okay in addition we also have a biomarker test.

Dan Krainak: Yes. Hi. This is Dan Krainak from the Office of In Vitro Diagnostics and Radiological Health. We'd also anticipate seeing MDDT submissions for qualification for any types of biomarkers in a variety of roles that biomarkers might be used in clinical trials anywhere from a patient selection for a prognostic enriched or other types of outcome measures.

(Dave Petrit): Great, thank you very much.

Coordinator: And next question from (Lauren Jackson). Your line is open.

(Lauren Jackson): I'm sorry. I'd like to withdraw my question.

Coordinator: Thank you. Standby for the next question; next question from (Eschar), your line is open.

(Eschar): Hi. Just thank you for your presentation. I was just wondering about the evaluation of these tools because I understand that most of the tools which are used need to be validated.

So is the qualification process different from validation? And if it is different, how will that be done? Will it be done by person who's using it?

So if you could please throw some light on that that would be helpful. Thank you.

Dan Krainak: Yes. Hi. This is Dan Krainak again from Office of In Vitro Diagnostics and Radiological Health.

We envision that as part of a qualification submission the tool developer would provide information and eventually data about the tool's validity. The intent of the MDDT Program is such that a qualified MDDT could – the data for that, the tool's validation itself, the validation of a tool could be qualified under the program and therefore additional or other medical device developers would be able to use that tool without providing the validation evidence for that tool in individual premarket submissions for example.

So I don't know if that entirely answers your question but if you have any additional questions or other response, go ahead.

(Eschar): So what I understand is that the validation be conducted by the person or the company or the enterprise who is creating or developing this MDDT.

Dan Krainak: Yes. I mean we would anticipate that the tool developer who's submitting the MDDT Qualification Package would be responsible for the validation.

However we encourage kind of groups, the developer, consortia, to cooperate together for the validation. So if there's an example of a tool developer who might have a great idea for the tool but needs to collaborate with others in order to collect the data needed for validation we would certainly encourage that collaboration. And then the submitter could be the combination of those entities.

(Eschar): Okay thank you.

Coordinator: Next question is from (Jennifer Barnes). Your line is open.

(Jennifer Barnes): Hi there. My question is do you anticipate in the future that regulatory decisions may be affected by the use of MDDTs versus tools that are not qualified?

Ron Schuchard: So this is Ron Schuchard from the Working Group. And a submission does not have to use an MDDT. It can use a tool that is not qualified. But then again that tool (will go) through the standard IDE process of validity and other things like that.

So the MDDT Tool would –the expectation is that it would decrease the review process because the tool would be already qualified for the use. So a tool can be used either as a qualified tool or a nonqualified tool. But it would

change the way that the Review Team would look at the evidence from that tool for the regulatory submission.

Does that answer your question?

(Jennifer Barnes): I think so. I think more so I was specifically asking whether or not an application would – if there was an MDDT for a specific purpose and a regulatory application did not use it that perhaps it would either be sent back or (unintelligible).

((Crosstalk))

Ron Schuchard: There is – sorry to interrupt but I think I now understand better. No. There is no obligation for a device the company is proposing in a regulatory submission that they use a MDDT. It is entirely up to that company to decide if the use of the MDDT is something that they want as part of their regulatory submission.

(Jennifer Barnes): Okay thank you very much.

Coordinator: Next question from (Dave Petrich). Your line is open.

(Dave Petrich): Hi. So my question is more about an MDDT that would be used as a reference method for naïve development or evaluation.

And what kind of level of software documentation would be needed to document an MDDT like for example like when the software is a component of the MDDT for the entire analysis? Like how much documentation do we have – do we need to have in place to support the MDDT?

Dan Krainak: That's an excellent question. Hi. This is Dan Krainak.

I think that would be an excellent question to ask in the context of an incubator phase submission to FDA. As typically the level of documentation for software for any type of premarket submission the FDA does depend on the risks and the intended use.

Similarly I believe in the MDDT Program the level of documentation necessary will depend somewhat on the advantages and disadvantages of the tool itself.

So a great way to kind of find out more information for a specific example because I can't answer for a specific example here would be to kind of submit a proposal for the intended tool. And then through those discussions and other discussions perhaps do the incubator phase or prequalification plan phase discussion, we can kind of hash out exactly what level of documentation would be needed for the software associated with that type of submission.

Ron Schuchard: And if I may just add, this is Ron Schuchard from the Working Group. Remember that the process though would be different. If you're submitting software documentation for a device then it would be towards safety and effectiveness whereas if you're submitting it for a tool the process that we're looking for are the requirements for validating a tool, these would then play into what you would need to submit for the software documentation.

(Dave Petrich): Thank you very much. I guess a question I may have now is like we've been using the pre-submission program right now to align with (OIR) CDRH on that aspect.

Is this program still appropriate to discuss those questions or is the MDDT Program now the best way to address these issues?

Dan Krainak: I believe if you're currently already in discussions - this Dan Krainak again. If you're currently in discussions with FDA about a particular medical device I would recommend that you continue along that pathway. If instead you want to investigate or pursue using that as an MDDT rather than a medical device there's a separate and independent channel to talk to the MDDT Program.

So and while there is some overlap in terms of the personnel who might be involved in reviewing those submissions, the MDDT Program is independent from the premarket regulatory pathway.

(Dave Petrich): Okay, thank you very much.

Coordinator: Next question is from (Ron Shallingold). Your line is open.

(Ron Shallingold): Thank you. My question is it possible for MDDT to take the form of a set of statistical tools for analyzing clinical data?

(Jay Vaishnav): Yes it is possible. Oh and my name is Jay Vaishnav and I'm here from the Office of Science and Engineering Laboratories. And yes, it is possible for such a tool to exist and be part of the MDDT Program.

(Ron Shallingold): And reason for the question is sometimes we need a combination, a unique combination of methods, statistical methods in order to arrive at a conclusion or at a decision about the validity, equivalence. For example of methods especially in the (IDD) area and especially with respect to qualitative type

methods which are more complicated to evaluate and judge equivalents on so in that context that would apply.

Dan Krainak: And so this is Dan Krainak. I think the breadth of possible tools that would be considered by the MDDT Program is quite wide. And I think that we would certainly take into consideration the type of tool that you're proposing.

The best way to pursue that would be to submit an actual proposal that we could evaluate in detail and try to consider with our – against our decision making criteria for both accepting a proposal and then eventual qualification.

(Ron Shallingold): Okay, great. Thanks very much.

Coordinator: Next question from (Jessica). Your line is open.

(Jessica): Hi. For those who are using a qualified MDDT, is there any further qualification they need to do or any sort of documentation that's suggested for using that tool?

Dan Krainak: So this is Dan Krainak. I think it would be certainly appropriate if a medical device sponsor were to use a qualified MDDT Tool but they would reference that tool. It is the intent of the MDDT Program that they would not need to provide any additional information about validity of that tool. If there were any considerations about a specific tool that should be included in the SEBQ which would outline any additional specific information that a user of the tool would be expected to provide.

(Jessica): Okay, great. Thank you.

Coordinator: Before we take the next question as a reminder please press star 1 to ask a question. Next question from (Rick Newman), your line is open.

(Rick Newman): Yes. I've got a question back to the biomarkers. I was just curious whether or not biomarker qualification within the context of CDRH, is there any coordination between the biomarker qualification that I know is going on within CDER within the drug side and how that other conversations between the groups on this?

Dan Krainak: Yes, hi. This is Dan Krainak again. Certainly we do collaborate with and communicate with our colleagues in the Center for Drug Evaluation and Research however we looked at the biomarker qualification within the context of the Medical Device Development Tools Program and then from the Biomarker Qualification Program in CEDR or the Center for Drugs.

(Rick Newman): Okay thank you.

Coordinator: Please standby for the next question.

Irene Aihie: Operator, do we have any other questions?

Coordinator: Thank you for standing by. We have a question from (Carol). Your line is open.

(Carol): Thank you so much. My question is on software development tools utilized to support medical device software development considered MDDT?

Dan Krainak: Hi. This is Dan Krainak. Again I'd just emphasize that the breadth of tools and types of tools that we would consider under the MDDT Program would be quite large. An important facet to whether we would accept a particular



proposal for such as software development tool would be the Context of Use components.

So and I think the best way to find out kind of about a specific example would be to refer to the guidance. Look at the Context of Use. Look at the role of that software tool or software development tool in medical device software development and determine if it would be appropriate for you or someone else who's interested in qualifying such software tool to submit to the program.

(Carol): Thank you.

Coordinator: Next question from (Dave Petrich). Your line is open.

(Dave Petrich): Hello. I just want to check, what's the change control requirement after the first approval of the tool?

(Andrew Yeatts): All right could you repeat your question please?

(Dave Petrich): Oh I just want to check to see what FDA's expectation about the change control or a modification after the first approval of the tool.

Ron Schuchard: This is Ron Schuchard from the Working Group, so if you're referring to a tool that has been qualified but then you may want to change it after it's been qualified...

(Dave Petrich): Yes.

Ron Schuchard: ...so it is expected. The guidance, there is actually a section. I apologize. I can't point to the exact section where it speaks to that, if you want to expand your Context of Use or if you want a different Context of Use, that it would be

expected that you would submit a proposal for that expanded or changed Context of Use.

And then you could work with the Working Group, with the MDDT Program, as to what would be needed to expand or change your Context of Use.

(Dave Petrich): All right, thank you.

Coordinator: Next question is from (Anita Sawyer). Your line is open.

(Anita Sawyer): Hi. My question is what do you folks estimate would be the average time the process would take to qualify a tool?

(Andrew Yeatts): Thank you for your question. I think that's going to vary widely over the type of tool, the Context of Use and the type of information submitted, how many phases. I think we certainly want to expedite this as much as possible.

But to answer your question what the precise number is really difficult without having a specific submission to talk about.

(Anita Sawyer): No. I appreciate the differences and the types of tools that would be submitted and, you know, the different phases of each.

But I just wanted to try to figure out, you know, the average time if you will. It seems like it might (unintelligible).

((Crosstalk))

(Andrew Yeatts): You know I think to give you some idea, you know, we – every tool would go through the proposal phase which we intend to get a response within, you know, 60 days so that's what it would take on our end.

And then if hypothetically you were to move to the qualification phase I think we'd intend to complete that review within three to six months. But then this is all very dependent on what is going on in gathering the data. If there's any feedback needed or anything like that.

But to give you some idea of the timeframes on that end. Those are the averages we're seeing in the Pilot Program. So hopefully that provides you some information.

But like I said it will be very variable based on the type of tool and then the amount of interaction that you would like with FDA.

(Anita Sawyer): And you sort of have another two phases to go through, right?

(Andrew Yeatts): Well those two phases are optional. So that gives us less. I guess it – you know some tools that you're seeing in the pilot are in the incubator phase would be tools that are being essentially worked on in a collaborative nature with us and the submitter. So it's, you know, more difficult to give a average timeframe there.

I'm kind of giving you the hypothetical that a tool was fairly well developed and what the timeframe would be on our end to look at that information.

(Anita Sawyer): I see it could (unintelligible) a year and a half or two years even maybe.

(Andrew Yeatts): And I think that's possible. Like I said I won't say that every – you know it potentially take that long if you're starting from developing a new technology and working with us. I mean it could take some amount of time.

But I think there's also technologies that might be fairly well developed but just hadn't been applied to this particular area. And it could take less time. So I think that's why it's difficult to say, you know, precisely. I do think we're, you know, we're committed to tools that will advance public health to expedite the review as much as possible.

(Anita Sawyer): No. I think it's a really good concept. All right thank you.

(Andrew Yeatts): Thank you.

Coordinator: That does conclude our question and answer session of today's conference. I'll turn it back to our host, Irene Aihie.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions, today's presentation. And transcripts will be made available on the CDRH Learn web page at [www.fda.gov/training/cdrhlearn](http://www.fda.gov/training/cdrhlearn) by Friday, September 1st.

If you have additional questions about today's presentation please use the contact information provided at the end of the slide presentation. As always we appreciate your feedback.

Following the conclusion of the webinar please complete a short (OC) Question Survey about your FDA CDRH webinar experience. This survey can be found at [www.fda.gov/cdrhwebinar](http://www.fda.gov/cdrhwebinar) immediately following the conclusion of today's live webinar.

Again thank you for participating. This concludes today's webinar.

Coordinator: Thank you. This is a conclusion of today's conference. You may disconnect at this time.

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