FDA User Session - Digital Health Software Precertification (Pre-Cert) Pilot Program

Moderator: Irene Aihie
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Coordinator: Welcome, and I would like to thank you for holding, and inform you that your lines are in listen-only during today's conference until the question and answer session. At that time, if you'd like to ask a question, you will press star then one. Today's call is being recorded. If you have any objections, you may disconnect. Now I'd like to turn to Irene Aihie. You may begin.

Irene Aihie: Hello, and welcome to today's FDA Digital Health Software Precertification User Session. I'm Irene Aihie of CDRH's Office of Communication and Education. On July 27, 2017, the FDA announced the launch of the agency's software precertification pilot program.

The FDA recognizes that we need a regulatory framework that accommodates the distinctive nature of digital health technology, its clinical promise, its unique user interface and the industry's compressed commercial cycle of new product introductions.

This is the first in a series of user sessions on the digital health pre-cert pilot program. As part of our commitment to keep our efforts transparent, the FDA will share updates throughout this pilot process. Today, Bakul Patel,

Associate Director for Digital Health in CDRH, and members of the digital health team, will discuss the progress that the agency has made on the software pre-cert pilot program.

The session will cover the program working model, which includes key program areas and questions that the agency hopes to gather public input on. The session will also include a discussion of next steps for the program. Throughout the presentation, we will open the lines for your questions related to information provided during the presentation.

Additionally, there are other center subject matter experts to assist with the Q&A portion of our webinar. Now, I give you Bakul.

Bakul Patel: Thank you, Irene and welcome everybody to the webinar and the first user session that we're holding. This is in our effort to continue to be transparent and collaboratively build the program as we have talked about since the day we launched the program itself.

Before we jump into the pre-certification program, let me walk you through the Digital Health Innovation Action Plan. In the innovation action plan, we talked about first aligning our policies to the 21st Century Cures Act, and we promised publications of many guidances. We did some of those guidances in 2017.

Along with the last update we did for the pre-cert program, we also announced the multifunction guidance. Let me touch upon that before we jump into the program quickly. So we talked about the three things we are doing in the digital health innovation action plan, aligning ourselves with the 21st Century Cures, building additional health units, and the streamlined - and exploring a streamlined review.

Today, I'm going to talk about this last component of the action plan, which talks about the multi-functionality guidance. Let me jump into that guidance itself. The guidance basically talks about how should FDA look at products that have many functions that may be devices that may be reviewed or maybe exempted, or maybe not - may not be devices.

How should we think about that? How should we review them? It proposes a policy of looking at the impact of safety and effectiveness on the function that is it medical device that's under review. We're looking at that very specifically. As it says in this particular slide, does it impact - the question we're asking is, does it impact or have a result on an increased risk, or have an adverse effect on the performance of the device in review?

So this slide basically talks about an overview of the entire guidance. We are encouraging people to comment on this guidance, but more importantly, let me just turn you over - turn over to the precertification program itself. This is how we are thinking about and you've heard me talk many times in the previous webinar as well.

We're looking at an organizational based streamlined regulatory approach for Software as a Medical Device as we start the program that relies on a demonstrated Culture of Quality and Organization Excellence.

Let me share a little bit more about the program to just level set everybody. The concept we started off in July last year, was to look at an organization, look at kind of the products, understand what the risk of those products would be, and include the confidence we can have in those companies that are building this product, and afford them an extremely streamlined pre-market review for products that need review.

For other products that are - that could be lower risk, can go straight to market with the commitment to collect and use the real world information that these digital health products, including software, can deliver. We're looking at opportunities to leverage technology that brings to us these products, technology that sort of affords us to collect information from these - from the users, from the products and use that to actually better create a system that actually will enhance everybody's knowledge. And at the end of the - enhance patient safety.

Thinking about that, we're also looking at using other information and evidence and using the programs like Nest that we're pursuing in other parts of the center to inform how well the program also operates, and how can we continue to improve and adapt to the changing needs as we learn more about the program. So truly in an iterative way, we're actually building the program collaboratively with all of you.

Let me just talk about how we are thinking about this. we're thinking about building the program with not only the nine participants that are bravely willing to sort of help us build the program in an extremely tight timeline, but we also are trying to engage everybody that's on the call today, and others who will listen to this call after the fact, and look at the working document to help us build this program.

Having said that, let me just walk you through what we had just released a couple of weeks ago on the working model. But before we get there, let me just give you an overview of how the session will run. I'll talk about the program itself, which I just did.

But I also want us to share some of the nuance - some of the things that we put

out in the working model, give you sort of a background on that. We also talked about how we can think about the program into four different components. I'll walk you through that. We'll have - we'll spend 15 minutes on each of the program components.

I have the team leads from the program areas that will give you a picture of what the program component scope is, what the goal of the program is and turn that into a question and answer session with all of you online. And we'll spend 15 minutes. We'll walk through the rest of the components in the program. And further, at the end of the webinar, we'll open it up for anybody who wants to ask any questions about the rest of the program itself.

If that is clear, let me just walk you through the components that we just announced a couple of weeks ago on April 26. We announced or we published a working model, which is truly meant to be a work in progress that allows you to see our current thinking as we sort of hear from stakeholders, hear from the pilot participants, and also hear some of the comments, and look at some of the comments we receive in the docket.

Taking all that into consideration, we thought it was beneficial for us to lay out our initial step, our initial concept ~~(unintelligible)~~ and what this program looks like. In the working model, we also highlighted a set of challenge questions, and these challenge questions are primarily intended to give people bite sized problem areas that we want help on.

This should be also looked upon as, how should we - taking those questions, if folks want to help us and actually solve this particular - these challenge questions, we would encourage you guys to sort of take a look at that and give us feedback on those - on solutions for those challenge questions.

The other thing we also said is about the roadmap. This is our commitment to being transparent. We will be updating this working model. We'll be sharing with you on a very frequent and periodic basis of what we are thinking, what we are hearing, give you an opportunity to sort of engage with us. At the same time, truly make it a crowd sourced collaborative building of this program. We want to hear from you and that's what we intend to do in this program.

Let me walk into the four big components and they don't stand alone. As this picture sort of illustrates, they are interconnected. And I'll talk about that in just a little bit and to just give you an idea of the four components. There is this excellence appraisal that understands what our organization's capabilities are and what their culture of quality and organizational excellence is.

We had proposed in the working model two levels as a starting point. We are looking to see how well they can sustain to keep it simple. The other component is about determination. Once the companies are certified, what should they do with their products they build and which - what can they afford in terms of going straight to market or to be reviewed?

The streamlined review, as the name sounds, it is actually about streamlined review. And the last part, which is about real world performance, and you'll hear a little bit more about what that means, but it's about what kind of information we want to understand when the product is in the market that can inform, not only you as developers of the program, us as agency and also help the program go forward.

With that, let me just revisit the five excellence principles we've proposed. We heard very clearly at the workshop we had in January, that these are the

five principles seems to be the right principles as we move forward. We're using this as a basis and a foundation to build the rest of the program, but we're really looking at these five principles as a thing that we would want to see in any organization/

Let me just turn it over to Cisco Vicenty and let him talk about the scope of work and that component. And having walked through what his thinking is right now and also share with you the intent of sharing what we shared in the working model.

Cisco Vicenty: So thank you, Bakul. And as I get started, I just want to also acknowledge and thank a lot of the people who are on the team who might be listening online working to develop this construct, this pretty complex portion of the whole precertification program.

But as we get into there, I'd like to just highlight that this piece, the excellence appraise list, let me focus on, you know, what are we developing that whole eligibility, the application process, how the FDA will evaluate or assess the organization's capability to develop that Software as a Medical Device through the lens that Bakul highlighted earlier, right, along those five excellence principles.

And this is really about the organization demonstrating their commitment and their capability regarding the patient safety, the product quality, clinical responsibility, cybersecurity responsibility and a proactive culture that's really able to monitor issues, respond to those issues, and incorporate that learning back into that system.

How well that demonstration is fulfilled, that's going to determine the level of the precertification that the organization will actually be awarded - given,

however we really structure that piece. The team is also working on developing how the organization sustains that precertification. And that's a little further down the line in the construct phase, but it's really that element of continual review and again, the adapted and continual learning.

A couple of things to just really highlight and note with what the goals and activities are within the excellence appraisal team. It's not focused on compliance to any quality system efforts at all. It's about execution. How well are you delivering.

The other piece of that is the agency is looking to really enable flexibility for the organization to leverage their basic internal quality system framework. Enabling a lot of, you know, what is the tools that they are looking to implement and apply? How agile they can be, and the big piece of this is really leveraging whatever good work they're already doing.

Let's not reinvent wheels where it is unnecessary. And that will feed a little bit later into some of the challenge questions we're talking about. This is a complex effort. It is something that we are continuously working towards. And what we did with the excellence appraisal and the precertification activities, and you'll see some of these questions out there right now, is try to highlight where we as an agency need some additional guidance or help.

As I mentioned beforehand, we really are looking to leverage as much of the good work that's out there as possible. These excellence principles are a great point of the agency focusing what do we care about to deliver on our mission and to the patient population while enabling as much flexibility as possible.

We want to leverage a lot of these existing models that might be out there, and

they all focus and get to the same things. But now we've given them where the focal point is.

Bakul Patel: So Cisco, thank you for that overview. And right now, we are on the slide which says, challenge question 1.1. It seems to be like one of the things that you've highlighted that you wanted to learn from, and how people help you with solving this. Can you just walk us through that, just in 15 seconds?

And I'm going to go to (Chuck) next so to ask, you know, we heard a lot from everybody. So (Chuck), from your perspective, while Cisco talks about it, can you share a little bit from your perspective, your engagement with us and how do you - how would you advise people to help with this portion?

Cisco Vicenty: So yes. with regards to the challenge questions, that's a great opportunity to just help us build and understand how you externally, if you're leveraging another set of standards and know the appraisal model already, how does that apply so that we are not asking or imposing something different?

A lot of the puts that come from there actually will fulfill what we're looking to develop in our requirements. So help us make that connection. That's really what the challenge questions are about.

Bakul Patel: So (Chuck), how would you help and guide the folks who are listening on the line who have not been deeply engaged in this discussion, but also seek help from those folks who are just hearing or seeing just the working model?

(Chuck): Thanks, Bakul. Thanks, Cisco. So to the extent that folks at home are not necessarily intimately involved with the pre-cert process. I would propose looking at the working model and then actually reviewing the challenge questions as Cisco and Bakul have laid out.

And from that point, there's quite a bit of material that has been put out into this space from the initial appraisal questions that I think Bakul had published. And then additionally, I think there were some additional conversations at the initial meeting in January.

And so using that as a starting point, I think one of the things that would be incredibly helpful is for folks to participate in a way where they can actually internally assess how they would potentially satisfy some of these proposed excellence appraisals.

There's a lot of ways to approach these questions and provide an input that says hey, we take these challenge questions and we're going to apply them internally. And I think from our smaller working group, the way we've approached, this is really let's provide the flexibility for companies, the eight or nine pilot participants to say, let's ask these questions more broadly and let's find a way for us to come up with our own proposed responses to these.

And what we found is actually - it actually fit really well within the challenge questions, although they were considerably less detailed I'll say in the way we pose these questions internally. But what we found is that if we ask these questions more broadly, pilot participants are willing to really put themselves out there and make sure that they're providing a thorough systematic look at how they would propose answering these questions.

Bakul Patel: Yes. That's really a good summary, (Chuck) and actually really good advice for people who are listening for the first time. At this time, I think I would want to open it up for everybody on the call to line up questions. but while people are doing that, I'm going to go back to Cisco and just say, just pick on

one of the things that - you used the words, use of standards and you want to give people sort of that credit back that we have talked about a lot.

Thinking about adoption of corporate level policies at a business unit level, what did you mean by that?

Cisco Vicenty: So there is - oftentimes an organization will be leveraging within their own structure, work that is already established policy or efforts for maybe the whole unit, the whole company that they're in or work that another unit has already done, for example in terms of leveraging a standard maybe around cybersecurity that they follow, or other reporting standards that they need to do, maybe even from a business standpoint.

That is all effort and work that actually helps fulfill or demonstrate your capability or your commitment, and not typically something that I think the agency is focused on now, but will help fulfil our excellence principles. Use that. That's really what that's focusing about.

Bakul Patel: Great. Thanks, Cisco. Folks on the line, if you're listening to this conversation and this is supposed to be an interactive session, for the next few minutes we'll take questions on this particular component, then we'll move on. And the whole idea, I know this is the first session, so I'm going to continue until - unless people have questions online, to just have this conversation with (Chuck) and Cisco here.

So we're actually providing the clarity that we're seeking. So let me just take another question at (Chuck). (Chuck) is a great pilot participant. He's been helping us build the program and giving us really good thoughts and ideas. (Chuck), if you look at some of the things that we have talked about as part of the appraising the maturity of an organization and how well they produce

products, anything that in a way that sort of we can rely on having them go to market.

What kind of - what lessons that you thought that we were asking that may - that was different or something new that you sort of learned that you could help orient people who are listening to this conversation to even think outside of the question that we've asked or help them answer some of the questions.

(Chuck): Yes. So Bakul, I think that's a great way to approach this. I think from our standpoint, the pilot participants and I really spent a lot of time actually trying to think like FDA.

And to the extent that it's difficult to put yourself in another standpoint or another perspective, I think one of the things that really helped us is - and I think it was earlier on in one of our site visits, I think one of the recommendations was to approach this as if we were appraising one of our supply chains.

Approach this is if we were appraising another entity we wanted to do business. And that actually helped put that perspective for us and say okay, well if we're going to appraise a business relationship with another vendor, company, et cetera, how would we think about this?

What are the things that are important to us to make sure that if they were out there and there was not a strong business connection naturally, how would we approach this?

And so from our perspective, that actually helped put us in the perspective of FDA, and we could actually turn that around and provide information back to

you in a way that I think was much more in line with the business language. And we were able to really interpret that and translate that to FDA.

And so from my perspective, looking at it like that, it was actually a very valuable tool.

Bakul Patel: Great. Thank you so much, (Chuck).

Coordinator: At this time, if you'd like to ask a question on the audio portion, please press star then one. That's star then one. Thank you.

Bakul Patel: Great. Thank you, Ed. Cisco, back to you in terms of how we think about and you talked about those four or five stages within the excellence appraisal. Can you share a little bit more depth in terms of what you're thinking of in terms of maintenance or anything else that you think long term, even though we're not addressing it right now. But any color you can provide to any of the questions that you have sort of asked.

Cisco Vicenty: Yes, I think - and especially with regards to anybody who is already working in the space in terms of their certification, type of activities to one of these other existing excellence models or maturity appraisals. The one thing that we are looking to do and drive towards is for maintenance in particular too is, how do we identify the metrics, right?

Somewhere in the software - the medical device space, there is the unique opportunity to really get a lot more real world data, real world evidence and have that learning and that knowledge and that demonstration actually feed back into the appraisal process and that maintenance portion, right?

So the maintenance becomes a standard of really feeding back in and not

necessarily needing the same level of insight that we collect in the initial onset from that standpoint.

Bakul Patel: Great. Looks like we have some questions online. Thank you, Cisco so much for that. We have a question online. We will go ahead and take that.

Coordinator: Our first one comes from (Tipton). Your line is open, (Tipton).

(Tipton): Hi. My question was, does this program apply to software as a standalone to medical device, or does it also apply to like embedded software and combination device software too?

Bakul Patel: I can take that. This is Bakul. I can tell you, the program is designed is for software in general. But however, as we start the program up and build the program, we are focusing right now in taking everything that is - that we can understand from the - from just software that is a medical device, which is in other words used to be known as standalone and use those - all those characteristics and learn as much as we can.

So the first part of our phase is about Software as a Medical Device or standalone software.

(Tipton): Okay. Thank you.

Bakul Patel: Great. Next - we can take the next question.

Coordinator: Next question comes from Joseph McBride. Your line is open.

Joseph McBride: Hello. I was wondering, what is the relationship between the precertification program and the Medical Device Single Audit Program? Is that - would that be considered part of the excellence appraisal or maturity assessment?

Cisco Vicenty: So that's actually a great question and this is a very different mode and model than what the Medical Device Single Audit Program is doing right now. The goal of the Medical Device Single Audit Program is really about harmonization within that medical device space.

Within the pre-cert program, right now as Bakul had mentioned beforehand we're starting with Software as a Medical Device. It has a lot more potential, but it was really geared about changing the whole dynamic and moving away from the compliance aspect and really focusing on the organization's delivery and a different way to really keep that pulse of that organization.

Bakul Patel: Great. So I know there's a couple of other people online. We will take - if you don't mind, hold your questions till the end of - till we run through all the four components and then we can probably take those questions. So if you don't mind, please keep the questions on hold. And we'll do the same thing for the other component. We'll work through the slides.

The next section is going to be about review determination, which is fundamentally talking about what should be done for review determination? What are the inputs to this component which sort of takes in the work that is going to happen in the excellence appraisal and bring it together with the types of products.

Imagine a place where you have very clear criteria, if you're making this kind of products, you appraise it at this level, you would know - as a user of the program, you would know whether your product or whether you as a maker of

the product, would have to go to the same lender view, or you would go straight to market.

We'd also - we're also looking at defining in this work product, the adoption of the IMDRF framework and the definitions. So we can actually be very, very clear at the end of the day what product ends up in what pathway. That's the intent of this program.

Without belaboring this further, let me just go to the challenge questions that we posed. One of the concepts we have in this program is to, how do you explore the definition statement, which is really a combination of intended use and a device description and indications of use together that was done in the IMDRF setting.

how do we take that and make it clearer for folks that are applying to this program in the US to align and also to find so that enough clarity that once we're in the program, once the reviewers look at it, users look at it, anybody else looks at it, have a very clear understanding of what that product is all about.

So we asked about the definition statement. We want to know, how can we refine it? We want to know, how can we better it? How can we align it to US regulations? And that's the intent of this question. I'm not going to read through the slides here, but I just wanted to give you that flavor.

With that, let me just ask (Diane) who was one of the pilot participants, who can share some nuance around so the intent behind this particular component. So (Diane), if I - if you - if I may, what do you think? You've known about the IMDRF framework. You've sort of studied it to detail.

And now as we use this in this program, how would you think about it that way? And the kind of clarity you think you need in the framework that I laid out from refining, aligning to regulatory restructure, aligning to what we know in the current regulatory structure, but not necessarily gravitating towards the - towards our structure, but really looking at clarity. What can be used from this framework that can provide clarity? So I'm going to turn it over to you, (Diane).

(Diane): Thank you, Bakul. One of the things that in this section that I think it's important to stress, because as participants, or at least for me as a participant, was it continues to evolve. The thinking around is that software is instrumented in such a way that you are getting real time information that you can act on. And that really does change the way you can look at things/

So if you look at - take a step back and you look at IMDRF and the risk classifications as they were developed, they're based on the reliance of the data, how much of it is the decision relied upon. Is it informing, driving treating? And what is the state of the healthcare of the patients? Are they just a little sick or are they very sick?

And these considerations can also be viewed through the context of how risk is defined in US statutes. So FDA in table three proposed kind of how you would interpret IMDRF in the context of our definitions here in the US. And I would really encourage the public to comment on the particular proposal in table three, because we're looking at different paradigms that are not necessarily tied irrevocably to historical approaches such as substantial equivalence and de novo classification.

And I think it's going to be really important for all the stakeholders to

understand that although how the classification, if I can use that word, is determined, it may be different, but we're still meeting the same evidentiary standards, perhaps demonstrating in a different way, but that the standards are the same and that patient safety is still a primary consideration.

So I think fleshing these out in more details and having all the stakeholders understand that this is in fact the case, I think will be very important to making everyone in the ecosystem supportive of this type of a program.

Bakul Patel: Great. Thank you, (Diane). That was very helpful. I think it gives a good framework for people to think about, especially as you look at it I mean from outside into the program. I think the experience that you have sort of brings that to the table.

Let me just share one other thing that (Diane) talked about, which is important sort of to think through is, not only we have some challenges because we are dealing with this extremely fast moving technology, but also something that does get - can be only recognized when it's described in the right way.

And one of the things we're looking at is how can we describe the product? How can we understand what does that mean for things like de novo? And what do we mean by substantial equivalence? How should we think about those things? And those are the questions you see.

So I would encourage people to think about - to look at those questions and answer - give the specific answers to us. we're looking at, in this component, to get input from the lines where we drew in terms of where things could be reviewed versus not.

We'd be getting input from the other components in this program because it'll

be dependent - as by the time you're done with the program, it will be dependent on what outputs come out of the excellence appraisal and what things we're expecting out of - to be reviewed. And then what real world evidence. So that's why when I said before, they're all interconnected.

I want to take this moment and open it up for the audience, people who are listening in to engage here and ask questions about this particular part and how - what kind of information would you guys need to help us provide those solutions? Now you have seen the challenge questions. You've seen sort of the concepts.

As (Diane) mentioned, we have a table that talks about an initial proposal of how we think from a risk perspective and what we could transfer the review or oversight to different parts of the program. So think - how would you think about that and what kind of information would you need to provide better input to us?

So it looks like we have a few people online ready to ask questions. We'll take the next question which is online.

Coordinator: Our next one will come from (Pat Hew). Your line is open, sir. Please check your headset or mute button. Our next one will come from Naveen Agarwal. Your line is open, sir.

Naveen Agarwal: Good afternoon everyone. My question was actually related to the challenge question in the previous section that you were describing about excellence determination. And you mentioned that the focus is on really the execution and not on compliance.

So I was just curious if FDA would consider also looking at their own internal

data from inspections or other enforcement actions and look at repeat issues or issues that seem to have a common underlying cause just to see if there are patterns, because my concern is that if you rely on external assessments and standards, there are so many of them out there that they will be - there may not be any consistency in reviewing the information. So I would love to hear your comments on that.

Bakul Patel: Yes. Naveen, great question. I think let's focus on - we'll definitely answer your question. We have 15 minutes at the end of the webinar to take those and some of the questions we didn't get to ask before so in the previous component.

But let's - I would like us to - I will - however, we hold off in answering that question after we've run through all the four components, it may actually answer your question. So let's go to the next caller who has a question teed up.

Coordinator: Our next one will come from (Ashkan Rizzoli). Your line is open. And again, if you'd like to ask a question on this session, please press star then one. That's star then one to ask a question. Thank you.

(Ashkan Rizzoli): Okay. I'm trying this now. Is this working?

Coordinator: Yes. (Ashkan), your line is open, sir.

(Ashkan Rizzoli): Great. My question is not about the challenge question, mostly about the status of the scorecard. And I was wondering how close that is to being done, whether there's drafts of it available?

Bakul Patel: Yes. So great question. This is Bakul. I think we will talk about scorecard down the road. We have - we are more focusing right now on making sure that we have the elements to deliver into the scorecard from the - I think the concept we discussed at the January meeting was more about sort of how to do you sort of visualize that output from the appraisal and how can that be then shared across FDA or with FDA or with others for that matter?

So great question, (Ashkan). But why don't we - I think we'll - since we answered this one, I wanted to - wanted just, folks, to ask question about the review determination part and the choices that we laid out in the working model. If folks have questions on that, I'll take them now.

Coordinator: One moment please.

Bakul Patel: It looks like we have somebody in the queue. While we're waiting for that to happen, (Diane), just to sort of give more insight into - to folks who are listening to this call and listening to this webinar, what would you suggest? Just like I asked the question to (Chuck) earlier, what would you suggest people should think about differently when we are co-creating this program together?

(Diane): So I'm going to respond more broadly than just this particular topic, because one of the things that I find most interesting is, especially as regulatory professionals, we're often used to thinking of this is the regulation and this is my SOP that supports it, and here is my documentation and that is where it's stored and that's what I take out and show an inspector.

And what I think I'm finding very interesting about the approach to this pilot is, it's not - back to what Cisco said, it's not about compliance. And the first

time he said that to me, you know, I really kind of struggled with, what does that mean?

But now as the months have gone on and the interactions have increased, it's more about getting credit for what you're doing, when what you're doing is being done for the right reason i.e. It drives the quality of the product. It supports the culture of excellence.

So that to me is a very different paradigm. So maybe FDA would be looking at slightly different aspects of the business than they would in a QSIT audit for example. But I think that it's very interesting that it's about what is your business doing? Is it - are they doing it for the right reason and how do you get credit for it? As opposed to this prescriptive taking and tying to a regulation. I think it's a very exciting concept.

Bakul Patel: Thank you, Diana. That's exactly the mindset we're looking for. We have a couple of people online while you were sort of sharing that thought. So we could take the next question.

Coordinator: Our first one comes from Agata Anthony Your line is open, ma'am.

Agata Anthony: Hi. This is Agata Anthony from GE Healthcare. I was wondering, with regards to the review determination and the IMDRF definition statement, has the FDA and the pre-cert participants attempted to tie the existing device classifications to the definitions in the IMDRF definition statement? And do all of those categories fall into the definition of a medical device as defined by the act?

Bakul Patel: It's a great question, Agata because if you look at what language we used in the review determination concept, and we actually use - we try to explain this

in the document itself is, we are actually revisiting the entire paradigm of ou0r classification when it comes down to Software As A Medical Device. They're reimagining and not trying to like fit in.

And the need for doing that is we have an opportunity here to leverage technology, leverage business practice and deliverable performance to make sure patients get the best options. So we are purposely not using the word submission, we are using the word review. We are purposely not using the word compliance, we are using the word excellence. I think that is by design. What we are looking at here is what should be reviewed when we know a company's excellence - where they fall - how excellent they are.

What should we review when we know we can collect this fantastic real work performance information that we can collect, because of the connected technology we have? So that's why we are not looking at the moment to classify in the traditional sense, but we are looking at it from taking a step back and seeing what's the best thing to do and what's the best oversight to do, to have for those products?

With that, thank you for this question and I apologize for folks who are in the queue to ask a question, waiting to ask a question in this section, but please hold your thoughts. We will take those questions at the end of the session, after we go through the last other two - the topics. With that, I'm going to turn it over to streamline review to (Adam) and have him talk through the couple of slides on what does it mean when you talk about streamline review and what's the scope?

(Adam): Thanks Bakul. I also want to send thanks out to the entire streamline review team as well as everyone who has actually joined today on this call, because this truly is a collaborative effort and we need your input into each one of

these pieces, to make sure that the program actually works in the best way it can possibly do so.

You know, as Bakul said, we have a number of different parts going on here and, you know, specifically within streamline review process, we are trying to set up a process for how we would actually receive, evaluate and determine the safety and efficacy of a (SaCMD) product, from a company that actually goes through the precertification process.

Now, you know, as (Diane) mentioned, you know, part of this is really to reduce the burden on both the manufacturers as well as ourselves and make sure that patients have access to high quality cutting edge technologies that are safe and effective. You know, when I break down the actual work that we're doing in this component, you know, and I'll do it very simply, into, you know, essentially we're defining inputs and processes.

And what I mean by that is, you know, we're looking at the inputs that are actually needed for the review process itself. You know, we're trying to minimize and streamline these to just what we need, to actually make that safety and efficacy determination. And part of this process is actually thinking about different ways we can get access to that information as opposed to the traditional routes of requiring it when a company brings a product in.

You know, we're also thinking about this, you know, setting up pathways for both new and existing products that we're thinking about this for, you know new products that have never, you know, never been seen before, as well as for modifications. And, you know, ideally the idea is to leverage existing processes that we have already in place, as well as to map out new ones that

can make it more efficient and at the end of the day, create a more efficient path to market.

And so part of this is actually identifying, you know, some type of interactive process we're conducing that review. And if you look at the challenge questions, which are now up, we've largely framed these around those two component pieces. And if you think about it, you know, you look at some of the examples in here, we're asking what product specific content would be expected to be reviewed in the pre-market and which elements could be shifted to be part of the excellence appraisal process or even all the way out to post-market?

And so that's what we're looking for, you know, help from the community is to really start thinking about what those critical elements are and where and how we can actually collect those.

Bakul Patel: Great. Thank you (Adam). As we'll get folks to line up to ask questions on this particular component, let me just ask (Larry) who is also a pilot participant, to ask a similar question I asked (Chuck) and (Diane) is (Larry), you've been in the industry for a long time, how would you think about this from a - completely from off the scratch of the clean slate? What was your reaction when we - when you first heard that and how would you help others sort of understand what we are trying to achieve here, so they can actually help us?

(Larry): Yes. Thanks Bakul. Yes. I mean this is an area where I think the rubber really hits the road. So this is kind of showing your work, so I would hope the - I would expect the public would have, you know a lot of energy around this, particularly after reviewing the working model. But, you know, I think as you mentioned, I mean there's a lot of room here for what I call practical

creativity. I mean we do have a blank slate here, so the intent of the, you know, streamlined review, is, you know, really to fully leverage the excellence appraisal on certification.

So I think, you know, taking that into consideration, you know, the materials that would be in the review for a product, as (Adam) mentioned, would be kind of an hour demonstration if the company does what they say they do. So there really shouldn't be any debate there. And they're following the processes that FDA has already assessed.

Bakul Patel: Great. Thank you (Larry). As we take on more questions on this particular component, let me just go back to (Adam) as people are lining - queuing up or trying to formulate a question. (Adam), you asked about - or you talked a little bit about, you know, shifting some of the - or revisiting and looking at during a review there are maybe things that we may not need to see or we may need to see differently and how we see it. So there is a content part and there is an approach and how we do it part. Can you talk a little bit more about that?

(Adam): Yes. And, you know, I'm not going to be all inclusive here when I say these things, but, you know, we're really thinking about what it is that a company is bringing into us. I mean when you think about, you know, some of the components of a software submission today and I apologizes for using that word, but when you look at it today, you know, you're thinking about the intended use, the device description, the risk analysis, configuration management, the clinical performance, labeling, etc.

And, you know, the question that we're asking ourselves is which of those pieces do we really need as part of that pre-market assessment and which pieces might be able to be, you know, be as (Larry) said, you know, can we

leverage some of the work that's going on in the excellence appraisal portion to help us get comfortable with those components instead. Or maybe they can be collected in the post-market setting.

So we're really trying to look at the different component pieces that make up a submission and ask what is it that we can get down to in terms of those minimum key critical components that we need to be able to see and review, to make sure that patients are getting safe and effective devices at the end of the day.

Bakul Patel: Great. So I think I'll make the announcement again to - we are taking questions right now, so folks who are like we said before, who are willing or want to have some questions on what we put out, we probably should think about asking those now, or we can take them at the end of the webinar. What - so let me just talk about the very first bullet that you have on this slide about specific elements itself. There - our current guidance on software submissions talks about a few components that we see today.

How would you think about that and what kind of input do you guys need from people as they're thinking about this program as a whole in the review process? Can you and (Larry) talk through that a little bit with us. (Larry), do you want to go first?

(Larry): Yes, sure. I think that - I mean to (Adam)'s point, I think, you know, identifying the value of being pre-certified, leveraging that and probably - I'm surprised to be saying this, but minimum viable review I think is kind of what we're talking here, for safety and efficacy. So I think from an excellence appraisal, (untellable) point, I mean if you look at the principles around cybersecurity, patient safety which I think takes into account risk management, product safety which takes into account how a company does

their testing and how they approach their testing, you know, what their processes are.

I think a lot of these systematic things could be leveraged in a way that no matter what product, you know, the company is developing, there would be just a kind of, you know, executive summary or some kind of summary of those activities. It's just that why you did the things you did and, you know, demonstrating that you were (unintelligible). So I think that would be, you know, one example. The post market side from clinical responsibility, if that's been assessed and there's a, you know, mutual understanding in the way that the company approaches (unintelligible) evidence, then maybe for a particular product there could be, you know, a very brief - I mean each company is committing to doing that by being part of this program and going forward in pre-cert.

So, you know, there could be a (straw) plan about that particular product, how they plan to kind of manage it in the post-market. Those would be, you know, a couple of examples.

Bakul Patel: Right. Thanks (Larry). It looks like we have a question before (Adam) gets to his part of this question. We'll ask the question. It looks like the next question online on queue.

Coordinator: It comes from (Scott ~~Steel~~thiel). (Scott), your line is open.

(Scott ~~Steel~~theil): Thanks and thanks Bakul. Question for you. In the model that is documented that you've shared, there's a spectrum of risk of product that's outlined within there and how those are identified. And the document doesn't call out this specifically, but the streamline review seems to be almost a one size fits all for any of the streamline review. Is that the case or are you considering and

looking at evidence that would be needed in the streamline review that would be commensurate with the risk of the product that's being assessed?

(Adam): (Scott), that's actually a really great question and one that we're still working through the answer to. But, you know, if you think through that process, I mean you could create a system where you're looking at, you know, a variety of inputs even though you're still looking at the same inherent process that everyone would go through. So depending on the risk you might need to have a little bit more information if it's a high risk device for instance, as opposed to a moderate risk device.

You know, I think there the difference is not so much in the process as it is how much information we're going to probably need to be able to get assurance. So you can think about it in that kind of a context that risk is going to influence the amount of information we get.

Bakul Patel: Yes. And I would also add to what (Adam) just said. I mean we are shooting - I mean as I said in the onset, we're shooting for simplicity, which means that the more nuances we add and more risk based stuff we have, the more complex the process becomes. And the whole idea for this reimagined paradigm, is to keep it simple that anybody and everybody who is wanting to take products to patients, has very clear path.

(Larry): Yes. And this is (Larry). I think there's a small element of kind of, you know, poetic license on the manufacturer's side that, you know, they would need to decide, we would need to decide what device specific materials that the company thinks is necessary to determine safe use. And I think - and then inherently there's kind of a big watch out there that, you know, we'd obviously want to minimize FDA requests for additional information, but a

company has to make that decision themselves. What do I need to provide to insure safety and efficacy?

Bakul Patel: So thanks (Larry). We'll take the next question, the last question on this topic and we'll move onto the next component. And then we'll open it up for generally, all questions across all four components, but I wanted to give this opportunity for the next person on the line.

Coordinator: Thank you. Your line is open (Sue Hiblen).

(Sue Hiblen): Hi. I was wondering how can companies that are about to submit new technology, be involved to answer some of these streamline review questions?

Bakul Patel: Go for it (Adam)?

(Adam): Thanks Bakul. I appreciate that. So I think right now you know, we're still in that formative stage for the actual process, but, you know, we do have a docket open, where we'd be happy to take your thoughts on how that could actually - what kind of a process would actually be more efficient and effective from your vantage point. I think as we get further on, it would be great to be able to pilot some of this with the community itself.

You know, so that's the other part of this is, you know, once we get further along and have a model that we could actually start testing, I think it would be ideal to actually start testing that with some of the products that people want to bring in house.

Bakul Patel: That's a great question and a great response. I want to just encourage people to - the reason we are being extremely transparent about this and being collaboratively trying to build this program, is not just for the people who are

having these products, but also people who are planning on doing this, people who have spent the time working on software, making products in other areas.

When they see those questions and when you hear sort of what the program is trying to deliver, please, please take a look at that and use those questions as prompts to that's where you can help it. So if you decide to help them, the entire program more than welcome. If you decide to work on one portion of the program, one question, that's more than welcome. So please keep those questions coming and like (Adam) said dock it. If you have questions on the program itself, general questions, without solutions, ask us questions, with the email box.

And we are also looking - you also see the updates going out. So stay engaged and provide us feedback. So great question. I'm going to pause here and turn it over to the next component and I apologize for folks who are about to ask a question, but please hang on and hold your questions until we get to the next component. Hopefully that answers some of the questions that we have been sort of getting.

So I'm going to turn it over to (~~Catherine~~Kathryn), to talk about real world performance.

(~~Catherine~~Kathryn): Thanks Bakul and I just want to thank the real world performance team and really all of the other components, because I think everyone in their talks' today, in this session, has talked about real world performance as an input to monitoring their specific component's activities. And so I think that it's an important aspect that I'd like to bring to light. So the scope of the real world performance team is really defining the real world performance elements and defining and developing the methodologies~~ythologies~~ needed for pre-cert program activities.

And we're looking at that at three different levels. So at first, the product level, we think that we can look at real world performance data to support post-launch product monitoring, to ~~i~~ensure ongoing safety and effectiveness ~~at (CMD)~~of SaMD products. We think that in the future that real world performance can also be used to make and modify product claims after a SaMD~~(CMD)~~ product has been on the market. At another level, we think that real world performance data can also inform at the organization level.

It can provide input to initial precertification. So if pre-certified companies ~~are~~ state what methods they're using and what product aggregate real world performance data they have can be used as inputs into their precertification status, as well as into that company or that organization level's maintenance of precertification.

Finally, we think that real world performance can be used to provide feedback into the pre-cert program overall. And so we think that organizational real world performance data could feedback into for example, the excellence appraisal team and we could look at modifying certain aspects of those excellence principles or what's looked at. Or it could also be used in streamlined review to look at what elements may or may not need to be reviewed in the future, for specific SaMD~~(CMD)~~ products.

And something that we wanted feedback on is what we mean when we say real world performance. And so in this case we're thinking about data relevant to the safety, effectiveness and performance of marketed SaMD~~(CMD)~~ products and that breaks down into, in our current thinking, three different areas, the first of which being real world health data, which could be inputs and outcomes related to the intended use of the SaMD ~~(CMD)~~ product.

We're also thinking that performance data could be related to user experience data. So outputs derived from experience related to real world use of the SaMD~~(CMD)~~ product. Finally, we're also thinking about product performance data as an aspect of real world performance data, which could be outputs and outcomes related to accuracy, reliability and security of a SaMD~~(CMD)~~ product. And this is something that we are looking for feedback on in terms of our terminology, and are we thinking about real world performance data in an accurate and comprehensive way?

Bakul Patel: Great. Thank you (Kathryn~~Catherine~~). Thank you so much for that background. I think this is - like you said, it was the most interesting part of the program that we all touched upon and we rely on as we move forward. Having said that, I want to open up the lines for people to ask questions about this component, before we get into - before I get into asking questions.

I also want to sort of point out that (Sandra) and (Ryan) are also participants that are on the line. And if they have an opportunity to think about - now that you heard all of the four components, what would you want to say to the people hearing this session? So (Ryan), do you - would you want to go first?

(Ryan): Sure. Absolutely. Thanks Bakul. You know, our experience in this program has been really eye opening to see how the other pilot participants are thinking about the program, about thinking about how it can be structured in the future. And I would really encourage others who are not currently pilot participants, from providing input because it's just been really fascinating to see how people are thinking about it in different ways I guess. And the more perspectives you all can get, I think the better this program is going to be.

Bakul Patel: Great. Thank you. Why don't we go to - take the next question online about this part? And (Sandra), I'll come back to you right after that.

Coordinator: At this time, if you'd like to ask a question on this session, please press star then 1. That's star then 1. Thank you.

Bakul Patel: Great. (Sandra), did you have any thoughts on this particular component that you want to share with the rest of the folks?

(Jeannie): Hi Bakul, good afternoon. This is actually (Jeannie) calling in for (Sandra). With regards to real world performance, I think with respect to the product that we had on the market and (unintelligible), I think that we had a great opportunity to collect real world performance data and use it to demonstrate the efficacy and safety of the products. In addition, I like to use this real world data to try to validate what the digital health team was doing with the streamline reviews. So I do encourage everyone in the industry, to…

Bakul Patel: Great. So we have some folks on the line. Thank you (Jeannie). We have some folks on the line waiting on the queue to ask questions. So we'll take the next one.

Coordinator: Our first one will come from (Anjut). Your line is open.

(Anjut): Hi. I had a question regarding complaint handling. So in this process will there be any difference for complaint handling? And how will that affect the pre-certification of the company if there are complaints in the field, from the real world data?

Bakul Patel: Well so if you look at what (Catherine) suggested, it's about user experience and product performance. Think about it from that perspective. So people, if

they're giving you feedback for - as we call complaints today, think about that as what does that mean in those terms of is the user experiencing issues? Is the product not performing or is it really having a topic or a condition that they're thinking about it from a real world health data perspective?

So that's how we are thinking about this in this world where really the information that is gathered from the performance of the product in the field, is really what we want to leverage.

(Anjut): Okay. Thank you.

Coordinator: The next question will come from (Hanji). Your line is open.

(Hanji): Hi. Am I audible? Bakul, this is (Hanji). My question to you is for some of the new technologies that we are trying out, the real world evidence may not still exist, right? So how much of such evidence would you really like us to have before we feel that we have a good starting point here?

Bakul Patel: So, you know, (~~Catherine~~Kathryn), do you want to take that question?

(Kathryn~~Catherine~~): So I think that it depends on a lot about the product that you're talking about and if you're pre-certified. But if I understand your question correctly, you know pre-certified companies that maybe ongoing and collecting real world performance data, you know, that could lead to what pre-cert status you have with the different levels that we've been talking about at this time.

Whereas if you're potentially a newer company with not as many products on the market or maybe not any SaMD ~~(CMD)~~ products at all, maybe you might be in a different tier with a pre-cert status because you haven't had that demonstrated track record of gathering that real world performance data.

Bakul Patel: That's a great answer there (KathrynCatherine). Thank you. And thank you for the question. I think it's important to - and this is exactly the feedback (CatherineKathryn) is looking for - is, are we collecting the right information? Some of it might be - already been collected, but be called differently. We're trying to structure that. I think that's what we are trying to do here. And if we can structure that it'll be useful for everybody. We'll take the next question.

Coordinator: The next question comes from (John Savak). Your line is open, sir.

(John Savak): Yes. I had a question. This is - this sounds a lot like the types of data that CMS and AMA are trying to collect around 99091. Are you working in conjunction with those groups?

Bakul Patel: So we - at this time, we - I mean other part of (CDRH) work with CMS all the time. But I think as we are exploring this and we haven't actually tried it in the real world, we - it's hard for us to sort of have that conversation. But yes, we - as we move forward and as we understand more exactly what can be done, and how it can be done, that's the least burdensome for both FDA as well as the people participating in the program, I think that's the better conversation to have.

So I totally agree. There's a lot of work being done in this area in other parts that can be leveraged and be benefitted - can be benefitted from. So I think that's exactly what we are trying to mirror. And how we do it that's closest and the most useful for not just people who are producing and us as FDA, but also patients at the end of the day. That's the most important part for us.

Next question.

Coordinator: Our next question will come from (Ashkan Rizzoli). Your line is open.

(Ashkan Rizzoli): Yes. My question is about, on this slide, what is the difference between the real world health data and product performance data exactly? I'm trying to figure that out and I can't quite see that clearly. And then I don't know if I'm allowed to do it, I'll sneak in a follow up question. On user experience, the IMDRS guidance encompasses both PDS and CDS offers, so patient decision support software.

And so when we talk about user experience are we looking both at, you know, feedback as the nine as, you know, the UI is not aesthetically beautiful versus let's say the UI for example, is actually difficult to use or causes the user to misuse this particular product.

(~~Catherine~~Kathryn): Sure. So let me take your first question. In terms of real world health data, we could be talking about things related to clinical effectiveness or adverse events or things of that nature, so outcomes related to clinical outputs and things of that nature. In terms of product performance, we could be talking about outcomes and outcomes related to cybersecurity performance of the SaMD~~(CMD)~~ product or the accuracy that that product has.

So in the health data aspect there's more of a clinical stint compared to the product performance which is specifically inherent to the software of the SaMD~~(CMD)~~ product.

Bakul Patel: That's exactly right. Thanks (Kathryn~~Catherine~~). Next question?

Coordinator: The next question will come from (Barbara Heglund). Your line is open.

(Barbara Heglund): Yes. I was wondering if the real world could be planned for in the products if we could help people to plan ahead by having requirements about what we're going to report, what sorts of things we're going to capture and what sort of criteria we're going to use to weight those things.

(~~Catherine~~Kathryn): So that is something we'd really be looking for feedback on. You know, we're currently thinking about the different data elements or analyzed data that could encompass these three different types of data that we're talking about. But we would really like to get your input on what you think we should be looking at as well.

(Barbara Heglund): Okay. Thank you.

Bakul Patel: Great. So this is a great segue into sort of opening it up broadly for the entire program. Now that you heard all the four components, four major components of the program itself, how we are thinking about building it, a little bit more deeper dive into what we had published in the working model, and you saw the questions that we asked in the working model and it gives you a color of like what we're looking for and the depths that we're looking for.

Hopefully this was helpful for you in terms of how we are exploring and what kind of input we need. So I want to open up the call - the questions from everybody on the call, to ask questions either about any of the four components that we may not have gotten to or not have an opportunity to sort of ask or answer. And anything else about the program that you want to learn about.

So this is probably a good time to open up for that. So let's get into the next question that we have lined up.

Coordinator: Thank you. Again, at this time, if you'd like to ask a question please press star then 1. Our next one will come from (Devoni). Your line is open ma'am.

(Devoni): Hi. Really great presentation - can everyone hear me?

Bakul Patel: Yes.

(Devoni): Okay. Really great presentation and really awesome program. The first question I had, I had a lot, but I couldn't ask them during the session, I seemed to always miss the exact time I could speak about it, was about the new guidance that came out on I want to say like kind of like modular submissions and how that relates to the pre-submission program.

Is that something where let's say you had a medical device where there's a hardware component to it and that part wouldn't classify as a software as a medical device, but you have other components that are software as a medical device, you could separate out your kind of submission to have, you know, one Part B submitted as, you know, through the regular process and the rest to possibly follow precertification? Like to be a part of the precertification program?

Bakul Patel: So the - let me just take a step back. I think you're asking about the multifunctionality guidance.

(Devoni): Yes, the multifunctionality one. Exactly.

Bakul Patel: So the point of the multifunctionality guidance is products have many components built into them, some of them are devices, some of them are not devices and some of them are exempt from review and some of them are not

exempt from review. The guidance talks about the policy of how the FDA is going to use - or what criteria it's going to use and what kind of questions people will ask if you have a device that has those components.

Now you can imagine, that is not necessarily meant to be that you can split your first submission. It is about, you know, when you're submitting something to FDA, if you have a component which is not a device, but it has an effect on - an adverse effect on the device component or device function, the medical device function within your product, that's - the questions we'll ask is what we are focusing on in that particular guidance.

So it's less about the regulatory path as opposed to more about how FDA is going to treat a submission that has those multiple things built into them.

(Devoni): Okay. And for that even if there is separation between a PMA and a 510K multifunction, you would - that would just be the impact of one on the other?

Bakul Patel: Exactly. I mean that's the whole point of that guidance is when we are reviewing a certain functionality within a product, what's the impact - adverse impact that can have on performance of the product that we're reviewing, from those things that we are not reviewing? So that's really what they're…

(Devoni): And it won't tie to the pre-cert in any way, in terms of having a hardware component? Let's say your phone has a component that is considered hardware, software as a medical device because of its functionality. And then you have other aspects of your software that are purely software as a medical device as…

((Crosstalk))

Bakul Patel: We had to think about this - I mean there are examples in the guidance documents that talk specifically about that scenario that you just painted. So I would encourage you to sort of look at that and if that raises other questions or comments or things that we should consider are very highly - I encourage you to sort of provide that feedback to us, to the docket, on that guidance document. Thank you very much for your question. Let's go to the next one.

Coordinator: The next question comes from (Garanji Samra). Your line is open.

(Garanji Samra): Yes. It's on real world performance. This is a follow up on that, our post-market performance. I'm curious if you can pull that upstream a bit, talking about possible solutions to that regards. So can we have something - like the pre or the post-market. The ideal beta site testing, you know, working with five or ten beta sites is not new. So - especially for new companies, right, they don't have anything in post-market.

So why can't the industry work with, and small companies work with, you know, some meaningful sample of five or ten beta sites and such, collect meaningful evidence, you know, pre or the post-market and have that substantiate, you know, via the streamlined review process or otherwise? And we are not even talking about, you know, the software developers they use. Obviously (unintelligible) and we are not even talking about the (sprint) demos and such that happens every two weeks, four weeks, six weeks anyway.

So we are not talking about that, but any sense of maturity of these software products going through the lifecycle, but really when they're ready for the primetime working at these beta sites and collect the pre, you know, pre or the post-market data and be able to substantiate. So that's one thing.

And another follow up on that is, you know, the - as you collect more and more field performance, even after you are commercializing, you know, the earlier idea of the frameworks with the metrics and dashboards, I'm wondering if clearing a field performance file or something like that, will make sense, you know, to gather the lifecycle activities before, during and after.

So ideas on the lines of real market performance there. Thank you.

Bakul Patel: Great. Thank you for those comments and they are great solutions and like you said, you were actually providing solutions. So we'll take those ideas into consideration. But I think in general I'll just respond back to the idea, is I think we do want to make sure that people use whatever information they can collect in either real world or beta testing or any other way they can do that, to get that high level of confidence that you - that we all need and everybody needs, not only the developer, but also the patients who we are serving. Thank you. Let's go to the next question.

Coordinator: The next question comes from (Tipran Nadic). Your line is open ma'am.

(Tipran Nadic): Yes. My question was as far as the program is concerned, is there like an overall schedule on when it's going to be rolled out officially? That's one question. And on the real world data, I also wanted - I had a follow up question regarding is there expectations on the duration of time we have to collect the real world data or expectations on how many months or years the device has to be marketed to collect this kind of data?

Bakul Patel: Yes. Great question. We haven't solved all of those details yet, but our - we have been talking about the concepts of - two ways - one is if the products that we're talking about in this space are an enabler in collecting this data, we

want those products to be instrumented that can collect the data first, because if we missed the opportunity to collect the data then we will never do it after the fact.

So that's one of the concepts we are trying to embed into this program, that people patriating in the program will do that. The second part of is taking into account where the products are. That's why the criteria that (Catherine) shared are generic, that can be applied across other products as well. So that's how we think about it. And that's sort of explained in the working model. But if you have thoughts and comments and there are use cases that would be helpful for us to consider, we'd be very open and looking forward to those kind of input.

So we'll take one more question after this, before we wrap up this webinar. I think we can go on for the entire day, but I think everybody's time is valuable, so we'll take one more question next, before we wrap the webinar for today.

Coordinator: The next question comes from (Matt Trachtenberg). Your line is open sir.

(Matt Trachtenberg): Oh. Hi Bakul. Thanks so much for sending out these challenge questions, so we can understand what FDA is focusing in on. I wanted to ask a clarifying question about the challenge question on cybersecurity. It says that cybersecurity issues often circumvent intended use and how can or should this be considered when determining risk level? Are you able to clarify what you mean when you say cybersecurity issues often circumvent intended use?

Man: Yes, hi, this is - that's a great question. And one of the things in that challenge aspect that we're really trying to get at is the agency recognizes in cybersecurity in particular, there's a lot that can be done ahead of time. But at the end of the day all of that is only as smart as the next person who really

wants to try to prove something or do something with the system or challenge their own capabilities.

So that's really about how do we incorporate the organization's ability to react to that, right, that assessment? How are they on top of that and how do they really take that and respond to that? That's really what we're trying to get at with that question.

Bakul Patel: Great. Thank you everybody. But before we go forward, let me just share with you how - where we are in the program. We are very early in the program, maybe not so early in the program, but 1/3 of the way into the program. What we are trying to do, if you see my slides, is trying to launch a pre-cert 1.0 by the end of this year. We will be looking at testing the program just like - I know one of the callers talked about testing the program and testing their products and trying it out and working out some of the issues.

So that's what we plan on doing in 2019. And we'll have another iteration that will go out at the end of 2019. But that's sort of the general schedule. I also wanted to share with you a way for you to stay engaged. We will be updating the working model on a frequent basis. When I say frequent, it'll be in the 30 to 45 day timeframe. At the same time we want to sort of give you additional information than what we had published before.

We plan on taking - we actually will be taking input on a rolling basis, so folks who are providing input to the program through the working model, schedule or other tasks, we want them to be sort of doing that as soon as we have these ideas put out and concepts put out for comments. We want you to stay tuned for future user sessions as we will continue to share our thoughts or feedback we have received so far, and hoping that we will build upon the feedback we get and some of the thoughts that we heard here as well.

I'm sure many folks had questions today that we couldn't get to. I would recommend that people look at the working model, provide their input and thoughts into the docket that we have continuously open. We also encourage people to ask questions about the working model. If you don't know what kind of solutions you - that we are looking for, ask the email that we have on the screen, FDA Pre-Cert Pilot email address. And then look for the program updates on the Web site.

We plan on doing this, as I said, collaboratively throughout the way, towards December, but we are looking for giving you information as we think, as we evolve, as we build the program going forward. So I want to thank everybody who participated in the program and I'm going to turn it back to Irene.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH Learn Web page at www.FDA.gov/Training/CDRHLearn, by Friday, May 18th. If you have additional questions about today's presentation, please use the contact information provided at the end of this live presentation. As always, we appreciate your feedback.

Following the conclusion of today's user session, please complete a short survey about your FDA CDRH user session experience. The survey can be found at www.FDA.gov/CDRHWebinar immediately following the conclusion of today's live user session. Again, thank you for participation and this concludes today's user session.

Coordinator: At this time that would conclude today's conference. You may disconnect and thank you for your attendance.

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