

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

**Moderator: Irene Aihie
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Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen only mode. During the Question and Answer session please press star 1 on your touchtone phone if you would like to ask a question.

Today's conference is being recorded. If you have any objections you may disconnect at this time. Now turning it over to your host. At any time you may begin.

Irene Aihie: Hello and welcome to today's FDA Webinar. I'm Irene Aihie of CDRH's Office of Communication and Education. The FDA recognized the need for 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 user session is part of our continued promise to be collaborative with all stakeholders in building the digital health Pre-Cert Pilot Program. As part of our commitment to keep our efforts transparent the FDA will continue to share updates throughout this pilot process.

Today Bakul Patel, Associate Director for Digital Health in the CDRH will discuss the recently release version 1.0 of the Pre-Cert working model, the test plan and regulatory framework.

These documents detail how the FDA has re-imagined its way of regulating digital health devices towards a total product lifecycle approach that enables the FDA to evaluate software products from pre-market development to post-market performance along with continued demonstration of the manufacturer's excellence.

Following Bakul's presentation we will open the line 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. I'm excited to share with you the updates we released on January 7. Let me begin with first thanking you all who have been contributing to the development and building of this program through 2017 and 2018. And now we are at a point as we talked about in January of 2018 that we will have a version 1.0.

On January 7 of 2019 we published a 1.0 version but before we get there and get to the testing phase of the program let me just start the discussion with how this program was imagined and what is it all about before we get into what we released. So let me just share with you what I'm going to cover today.

We are going to cover the background of the program itself and I'm going to share briefly what has changed as this is a continuous update to the program. And we encourage questions and input along the way for the program itself through the docket. As well as today we have an opportunity to clarify what we put out and perhaps inform us of what you think we should be considering going forward.

So the three documents is something that we'll cover today and I'll focus a lot on the test plan itself today and help you understand how the program is testing this concept and how it's going to go forward and realize the potential of what we are trying to propose in the concept we've all imagined to be.

There will be a lot of opportunity for you to ask questions so get your questions ready and we'll be here to answer those questions. I have my colleagues here with me and they'll answer those as well.

Let me start from the top. Digitalization has actually affected and touched all of us and it continuous to touch as these all tools are rapidly evolving and to keep pace with those FDA as Irene mentioned earlier does need to look at how we should oversee these products with the goal being having patients afford the access of high quality, safe and effective digital health tools.

Having said that I think this is about efficiency, this is about optimizing their oversight, this is about making sure we provide a great experience while maintaining the standards of safety and effectiveness that we are responsible for holding. And as a community and when I say we I include you industry, you providers, you patients as a partner in this how do you keep that confidence high for these products for the same potential that we all want to realize.

Let me just start with how we got here through 21st Century Care Act and the User Fee recession I think collectively we recognize that there needs to be a constant update and a refinement of our policies going forward especially in this area.

We also need to build the best trend and expertise at FDA recognizing that we have to do a few things here. But more importantly we need to start reimagining how do we tailor our oversight that aligns with the commercialization of these products, the way they are built and actually be closer and closer to how products are developed and delivered to the marketplace and used in the marketplace.

So having said that, we envisioned this program a year and a half ago now when we said, what if we go to an organization trust and comparing it to what we've said in the past to the pre-check program that other agencies use to other comparable systems that once we know and trust the folks who are making these products can we get to a place where we can make sure that the products made by those organizations are also trustworthy.

So an organization based regulatory approach combined with a product based regulatory approach is something that we are imagining. So in this case what we proposed was can we rely on the cultural quality and organizational excellence of the organization and then we can trust what efficiencies can we bring to the table.

So let me just talk about the principles and the intent of the program itself and the basis of what we've started. Patient safety is top most on this list and we want organizations to exhibit that that they include everything they do in the path of creating, conceptualizing to making, to delivering and maintaining products with these items both in kind. Starting with patient safety, having

great product quality, being responsible clinically, being responsible in the cyber world because that's an important emerging area.

And then as the heart and the foundation and bedrock of all sites we have today is preventing problems by having a proactive culture as well as making sure that we're kept in the FDA and the public are prepared for things that could go wrong and can be prevented.

So with that in mind our goal for the new model was can we trust organizations? Can we leverage transparency where everybody knows everything about not only the organization but also the products?

And then in exchange for that can we tailor our oversight specifically on the pre-market review side -- and at the very least complete the cycle of this total product lifecycle concept by making sure we have a robust real word performance and performance analytics that can be sort of looked at to make sure and give us the assurance that we all need and give the public and the user the assurance we need.

Let me share with you a familiar picture which I have shared since day 1 of this program. This concept is really based on the total product lifecycle that I have been talking about and we've been talking about as a group and has been becoming very popular.

So how do you take this and really make it very real is really what we are on the journey for and today we are trying to build the top portion of this picture while thinking in the background how do you make sure that this program can also learn along the way.

So what we are witnessing in the last year and a half and going forward is it continues learning not only the expectation for the makers of this products but an expectation that we are creating for the regulatory system to be learning as well.

So let's just jump into the three documents we've published. As you can see the very first thing is the working model and we've moved from - it moved to version 1.0. We included a few more details to the content however, I think we were also missing some of the other pieces which is why the other two documents come into play. The regulatory structure, what we are going to use, why we are testing the program and the plan of how we are going to execute the test itself.

So getting to those details in a second but those are the updates we just published and we wanted to make sure that everybody is on the same page also understanding what've published and the context around it. So today's Webinar is about getting into a little bit of those details.

Let me share at a very high level what we added into the version 1.0 of the working model. We emphasized that this program is all about the total product lifecycle. We are emphasizing that we are in the excellence appraisal process and we describe what that detail looks likes.

We are also looking at how do we create a system that there is very minimal questions on the product what category it fits into aligning with the international medical devices regulatory form or framework. We also propose a list of review elements from what we currently ask and said, "We think if excellence appraisal and the redetermination happen these are the components that are important for us to review." Again, these are proposals that we are going to test and I will share with you how we are going to do that.

And again at the end of the day we added a lot more detail into the real world performance analysis plan that we expect to observe how well the companies - how we can test the program to see what measures and metrics we should use or what signal we should measure or observe to get that continuous assurance of safety and effectiveness.

We are moving really from an episodic oversight to a sort of a continuous oversight where we are not only looking at one point but looking throughout the lifecycle. So I want to emphasize that and that was emphasized in this working model that we just published.

This picture embodies the description I just talked about in a complete total product lifecycle where it's not about just entry to market but is also continuously right in the market as an insurance. Again, a lot more details to be flashed out but it's actually the intent of the program and we continue to drive that as one of the things that we want to achieve in this program.

Let me share a little bit about the structure that we are going to use in this year for testing the program itself. We've propose a De Novo pathway that we would then look at the information use in the excellence appraisal, the redetermination and streamline review in totality to assure that risks of this product are managed and controlled. And that's how we are looking at it.

We propose that one can submit a redetermination pre-cert to get some of those questions answered ahead of time plus also figure out how this product fits into the framework and where it would fit. We envision down the road once a De Novo is set up and a classification set up of those principles we would be looking at further down the road opportunities to look at how do we think about this from a 510(K) or a substantial occurrence perspective.

Again, we don't anticipate using all of these components especially the last part of 510(K) in this one year time frame but we are - what we are saying is we are going to start with the De Novo process where we can establish how excellence appraisal, the redetermination and real world performance can be thought about as risk mitigations in a product.

Let me jump into the test plan which is probably the most important, most immediate thing that we need to cover today. Let me start on the top on this.

The objective is we have a current process that gets products to market where we get our reasonable assurance of safety and effectiveness. We want to compare how excellence appraisal combined with the streamlined review can get us to the same answer.

What we envision here and we've shared this in our documents is, we imagine the sponsor would submit a traditional submission as of today and in this case the test plan participants would submit a traditional application in this case and we'll do a kind of a - we'll conduct a review. We at FDA in the background we'll work with the companies to do an excellence appraisal and we'll figure out what parts of that would actually be reviewed and we'll compare that.

Let me explain that a little bit more. We anticipate during excellence appraisal first when a submission comes in you take out portions of that we would have a review team look at can it get to the reasonable assurance of safety and effectiveness. On the bottom you'll continue the process of reviewing the product as you would normally do but compare the two outcomes of can we reach the same conclusions in these different ways.

One other thing that we are looking to sort of iterate in this year is learning from those gaps. Learning from those, learning from between the top half of this page to the bottom half of the page. How do we sort of take those learning incorporated into building this program further?

So we are iterating, building and testing at the same time so you will see we are planning on refining the program going forward and again this back to that spirit of this learning regulatory system that we want to set up. And we are going to do that before we actually move forward.

For folks who are going to be part of this test plan who are coming in, the pilot participants and others who their submissions that would go through we would - they would see the bottom part which is normal submission. They will also experience excellence appraisal and partner with us to figure out what the review and the refinement looks like.

But from regulatory perspective it looks no different than what we are doing today. So that's an important thing to keep in mind is the review and the decision to put a product to market with the same assurance of safety and effectiveness still continues to go on as what we've been doing in the past. So that's the foundation and part of the steps approach.

But at the top we have this opportunity to experiment. We are going to experiment on different aspects of the program itself.

So let me just share with you what we are thinking about in a little bit more detail. We are looking not to provide a certification from an excellence appraisal and the fact is we can do that because we don't have the benchmark to say you are above this threshold or not.

What we're saying is, we are going to look for the same information while we are doing excellence appraisal so we can then look at that information along with the streamlined review component - the portion of the review of the submission and see whether we can come to a conclusion.

Number two, we do propose starting with De Novo as I said earlier because that's our existing authority. We are working in collaboration with FDA review divisions to make sure the experience of those folks who are going to the test plan still remains high and that's very high up in my priority -- and high up the center's priority to make sure that we are not disrupting not just the review divisions but also the sponsor's expectations and experience along the way.

Let me tell you what we are also trying to do innovatively in this program and why we are testing. We are exploring ways to capture additional test cases for the program and settlement.

And we'll be looking for opportunities just like we have done in the past - last year looking for input, feedback and opportunities to test out various portions of the program. So that is something that we are absolutely looking to do. We are going to - we are going to iterate that's a given. But the iterate is going to be for us to get better at what we are doing and remove inefficiencies.

Our submission process and approach will be iterated as well. We are looking at creative ways to make sure that the reviewers in the agency have the fullest experience as well as the sponsors and folks can get all the full experience as we sort of move forward with maximizing efficiency. A reduction in effort on both sides of the sponsor side as well as for the FDA side.

So having said that I'm looking forward and the team here is looking forward developing the program with the stakeholder's input. I really need all stakeholders and we strongly encourage everybody as you have continued to do is provide input to the working model, provide input to our test plan.

Come back to us with your ideas and submit them to the docket. We are very eager to sort of see your ideas as we sort of flash our thoughts out as well. Your input will really help us shape the next step as we go through this program. So I'm looking forward to it.

Just like before we said March 8 is the time - the timeline to provide input but that's - the timeline we've given you for us is a control aid but we are really looking for input throughout the year in this program. And that's something that we are doing very unique here in this program as we're developing it.

We are collaboratively building the program with everybody so we get the best input, we have the richest information to build the program. I'm going to just to show on the screen some of the resources. If you haven't been there, go to the docket, go to our digital health Web page and look at the information we've published.

I'll even ask further if you think that we are not clear on our Web page, we are not clear in our communications please reach back out to us at either fda.digitalhealth preferably if you are specifically talking about this program and the pilot send us an email and tell us what would you like clarification on.

And we have a team working really, really hard to make sure that we are explaining our intent, we are explaining our concept clearly to folks -- because I can imagine we have a lot of content that may be not so easy to follow or not

so easy to sort of grasp. So please reach out back to us and that interaction itself is information to us.

With that I think we can go to questions and ask - ask folks to be ready to ask questions on the content you have seen already. We purposely have this Webinar today to allow enough time for folks to digest, read and have some questions so we can answer them. In the room we have folks on the team who are ready to answer questions and we'll take them now.

Coordinator: Thank you. Participants on the phone if you would like to ask a question please press star 1 and record your name and your company. There will be a small delay as your information is gathered. Again that is star then 1 if you would like to ask a question.

Bakul Patel: So while folks are waiting to ask questions, in the room I have Marisa Cruz (unintelligible) and we have Cisco Vincenty in the room and representing various portions of the program.

Let me just ask a general question to the team here and perhaps we'll start with Cisco and say, I know there is a lot of effort going on in the center and you are a part of the Case for Quality effort as well and this third integration working in the Pre-Cert.

Can you clarify for folks who have been wondering about how Case for Quality and Pre-Cert program and excellence appraisal from your perspective what questions have you received and what clarification that people are seeking?

Cisco Vincenty: Thank you, Bakul. This is Cisco Vincenty. And just for, you know, some of the people who are engaged and often times what we hear feedback on is the

fact that the center has got so many different pilots, so many activities going on. What right for me? How do they touch? What integrates where? Where can I get credit?

The idea here and what we we've been doing from a Case for Quality perspective is really try to learn about that aspect of applying an excellent approach and an excellent smile to the med device industry.

What can we truly learn? Is it applicable? Does it really give us the same assurances that we would get from a compliance inspection so that there is no missing gaps? That's the type of information that we've been able to translate now into the idea of what the Pre-Cert program is doing from excellence appraisal standpoint.

We can actually get to the information that we need. The approach is solid. It drives a proven mindset. But from what Pre-Cert is doing where they are building the full structure right upfront the program is looking to leapfrog what we had started in Case for Quality where we are transitioning portions of what the med device industry is doing right now to a similar construct and model.

There was a lot of learning, there is a lot of overlap between the two efforts and the two activities. So eventually there might be a convergence into how these two programs start to operate and what really is leveraged and the benefits that are given. They are just right now satisfying to distinct very different needs and on a (unintelligible) and kind of, you know, just unity between the two.

Irene Aihie: We'll go ahead and take our first question. Thank you, Cisco.

Coordinator: Excuse me speakers. We do have a few questions from the phone if you are ready to take them.

Irene Aihie: Yes. We're ready.

Coordinator: Thank you. The first one is going to come from (Danny) from Medtech Insight. Sir you may begin.

(Danny): Hi Bakul. Thanks for holding this webcast. I wanted to ask, you mentioned that you are going to experiment on different aspects of the pilot program. Could you elaborate on that?

You know, what kind of aspects are you looking at and also can we expect that each of the nine participants of the pilot program will maybe see a slightly different path for you guys to figure out which part is the most efficient?

Bakul Patel: Of course. Yes, I can talk about that. So for example if folks are interested in us working with - we're working with you on excellence appraisal we would be open to looking at that. Of course we have limitations on timing and the resources on our hands and so I think those are the kinds of inputs that we're looking for.

Also along the way we may find questions on metrics or an analytics that we may want to get and if we have ideas of how you are collecting as a company those real world analytics, how those tail into the model that we've proposed we would be looking for those experiences as well.

So you don't - I guess how I would summarize this is that you don't have to have a complete end-to-end engagement. You could have portions of the program that you can engage on.

Coordinator: Thank you, speakers. Our next question comes from Mr. (Salentino) from TELUS. Sir, you may begin.

(Salentino): Yes. My question was around the same thing like (Danny) the experience on different aspects of the participants and viewing the different efficiency paths that you have. But you pretty much answered it. Thank you. I appreciate it.

Bakul Patel: Next question. So while we are waiting for the next question to line up, Marisa can I ask sort of teeing up from the last response we gave. What would you recommend or what would you say would be really interesting for you to learn from folks who are willing to share real world performance analytics?

Marisa Cruz: Sure. This is Marisa Cruz. So I think one thing that we're really interested in learning over 2019 is how to figure out the right balance between the number of metrics that we collect and the ease of sharing.

So we are looking for metrics that are meaningful, that affect decision making but that are not so complex or onerous that it creates more burden for the sponsors of products and it requires a lot of additional context as the FDA is looking to interpret those metrics.

So we are looking for companies who have differently situated products - products across different risk problems, differently structured organizations to share with us what metrics they are currently collecting -- such that we can try to figure out what that balance might be to minimize burden but to create some useful metrics and a repository of metrics that we can use to ensure ongoing excellence in the post market space.

Bakul Patel: Great. Operator, can you ask the next question to be asked?

Coordinator: Absolutely. Once again, if you have question at this time please press star 1 and record your name and company. The next question comes from (Ryan Fischer) from Experian Group. You may begin.

(Ryan Fischer): Hi Bakul and the FDA team thank you for the information today. A quick question to clarify sort of the scope of the working model 1.0 and the testing that will be done in 2019. Is that limited to the existing 9 pilot participants or is it open to expand to other new participants through the Pre-Cert and De Novo process if you can clarify?

Bakul Patel: Like I said, I think we are looking for opportunities to explore how we would get other experiences into the program itself. And like I said in the previous response, we are not just necessarily looking for ways to experiment and test through the entire end-to-end from submission to end.

But what we are looking for is how can we get more information and more experience for example excellence appraisal, you know, performance. And perhaps there are innovative ways that folks can come up with and say, here is how you could do a review of the product with this - this component. And it doesn't have to be live where you are targeting a product that's trying to get to market.

I think folks have to realize that this is going to take a little bit more extra work because we are going to experiment and the fact that we are going to experiment we'll add a little extra burden on both us and for the sponsor.

So what we don't want have to happen is the test program to be in your way for a product to market. So that's the foundational thing that we want to make sure that it happens while doing the test period. So that's the idea.

We are going to look at the 9 pilot participants to look at test cases. And in the future as we get more experiences and we get more ideas from folks we may consider other things that but that's then starting point.

Coordinator: Thank you speakers. The next question comes from (John) from EMD Serono. You may begin.

(John): Hey, thank you again for today's presentation. The pilot diagram included a De Novo pathway indicated that you would submit your traditional 510(k) and the software will be reviewed under this program as well concurrently.

So since its going through a De Novo pathway which typically it implies that there is no predicates is the assumption is that you will not need to identify your predicate - a predicate device to support such an application if it proceeds through this pilot.

So for example if you develop a mobile app that has a dosing that is for say dosing insulin where clearly there is (unintelligible) clear predicate today. Would you need to include such a predicate or would it simply go through a De Novo?

Bakul Patel: Yes. I think it's going to be harder for us to start off of an existing predicate for that particular product to do (unintelligible) care. This is why I think before we get to your 510(k) where there is substantial equivalence the neutral question. We are suggesting that we are starting with the De Novo type products. They are the best candidate and most ideal candidate to test the program and that's really what we are talking about.

As you can imagine there is complexities from a regulatory perspective to consider how do the risks manage for a previously classified product if you are going through an excellence appraisal and real world performance.

So those are the challenges we have from a regulatory perspective and that we need to manage. Sol the painless way for us to think about this is through the De Novo pathway.

(John): Okay. Thank you.

Coordinator: Once again if you would like to ask a question please press star 1 and record your company name. It looks like we do have additional comments from (Danny) from Medtech Insight. You may begin.

(Danny): Hi, thanks for taking follow up questions so I have got a couple. One, earlier you mentioned that the Case of Quality is running parallel to the Pre-Cert program and it's leapfrogging. Could you kind of talk about where you see a potential convergence of the two?

And another question I had is, you talked about - I wondering if there was a timeframe for major mile markers over the next year that you are looking at that we can kind of see, like, this is when we expect an update on the model and any sort of other documents that might come out.

And third, I wanted to ask about, you know, some questions about the legal aspects of the program in terms of whether you'll need any more congressional authority to run the program. As you've been working on it have you considered those and have you come up with an update what kind of it any legal authority you'll need in the future to expand the program.

Bakul Patel: Thank you for that question. I think it's really insightful for you to ask that question. Let me tackle the latter part first about what kind of update and maybe you had three questions in your question so...

((Crosstalk))

(Danny): Yes (unintelligible?) the legal one in the Case for Quality. Sorry.

Bakul Patel: So the Case for Quality - let me answer the other two questions and then I will turn it back top Cisco to answer the Case for Quality question.

So you asked a question about how often can you expect updates. We will be looking at ways to provide updates along the way. I would say we are definitely looking at a way to provide an update media of some sort as we haven't defined what that looks like yet - either a publication or a Webinar.

But we intend to sort of do this along the way and it will depend on many factors - the number of test cases that we've gone through, do we have enough information to share that's interesting to folks and the number of inputs we've received so far in the docket.

So those are the factors we will be looking at to provide an update as we move forward. So that's the question you asked.

So let me answer the question about authority. The entire year for this program is to understand things that we need to get efficient done and fort his concept to realize. And one of the things we will be looking for along the way is what if inefficiencies are created because of your testing? What if we can create efficiencies or opportunities exist because we are testing, what

opportunities exist because we don't have certain authorities and that could be leveraged going in the future.

So as we learn those things I think that's when we will be able to determine if we need or don't need any additional authority. I mean, as we mentioned in our regulatory document that we put out its exactly that. At FDA currently we think we are yielding all kinds of parties but there may be possibilities that we may need to think about something differently And I don't know the answer to that.

So identifying those items now at this point in time is probably not optimal but along the year we may learn and that's the idea for the testing.

So I'm going to turn to Cisco and talk through - to have him talk a little bit about Case For Quality.

Cisco Vincenty: Hi, this is Cisco Vincenty and let me just make sure I remember the question and if I don't touch it completely please feel free to ask again or cover what's missing.

In addition to that I just want to remind everybody or just get it out there that if there is any information that people are looking for any additionally on the Case for Quality you can visit our Web site for Case for Quality to get to learn at least high level details and get some information.

But from a pre-certification program standpoint the whole program, right now and this is really driven a lot by the need of the actual product base and solution that's trying to solve in digital health. The need for that rapid churn what happens within industries a lot other points that I think Bakul highlighted early on in the presentation.

That drives having to build a completely different structure approach for the way we do and approach oversight and regulation and review of these products so to the point where we're leapfrogging is right. It is a more robust - total product lifecycle model that is being built from the pre-certification program standpoint. And that's intended to start after that in that fashion.

With Case for Quality knowing that we need to also rethink things and look at things from a total product lifecycle standpoint we started with really trying to understand what's the current state of what our practices have been with industry. Where are they? What's the capability of, you know, monitoring or addressing or changing the way and dynamic of how we really oversee and apply our tools.

We've also been able to see what that capability is from our review side to try some of that streamlined perspective with a subset of types of submission. So the elements I think that have been put together for Pre-Cert in some small scale and relatively, you know, confined sort of spaces have been able to prove out with the Case for Quality set of activities.

And now it's just a matter of really getting the other elements of the evolution for that maturity phase that we're tackling right now in Case for Quality to keep moving on in the course of this 2019 timeframe. So that we can get to the point where the same kind of approach that I think Bakul is really trying to implement here with the pre-certification program we can also leverage even from just a regular hardware medical device standpoint.

There is a lot of benefit to be able to get, you know, that incorporation knowledge with the real world data really streamlining and refocusing what

happens during the review phase so that product's issues and corrections can be addressed a lot faster and in a more relevant fashion to the patient.

So I think that's pretty close to what's happening.

Coordinator: Thank you, speakers. Once again if you would like to ask a question please press star 1 and record your name and your company. One moment as questions register. It looks like our next question comes from (Michael Curling) from DCH Alliance. Sir you may begin.

(Michael Cowen): Hi, this is (Michael Curling) and I'm very appreciative of this Webinar. And the questions I have relate to the excellence appraisals. I know that FDA is considering accreditation of third party appraisers, can you talk a little bit more to that?

Bakul Patel: Sure. I'll tee it up and then Cisco can sort of address the third party part. So the concept of third party for the proposal is it's not something g that we are testing in 2019. So I just wanted to make sure that we are clear about that.

And the fact is we need to determine what process we would use for excellence appraisal, what method we want to use because we are really shifting our focus from process based appraisal to an outcome based appraisal.

What I mean by that is, if we can understand the outcomes of the processes and know the processes and the assurances of the process itself and that method and that process of appraising is still under development. And in one of those things is we will look at what better makes best sense. And further down the road we will consider the third party program.

Cisco, do you want to add anything to that?

Cisco Vincenty: Not a significant amount. I think you captured it best. We are looking to learn since the model we are developing really incorporates a lot of what we found were best practice across the board. And it's also trying to drive things from the different perspective of just looking at a traditional compliance audit.

It takes - it really does need I think us FDA onsite throughout the course of the first year so we can capture, engage what we are putting together is really addressing our needs not just from the baseline regulatory standpoint but from the two excellence principles.

Once that is done and captured that is then easy to put out and a lot of existing models, a lot of existing third parties are very easy - easily adapted to what's in that construct.

Coordinator: Thank you speakers. The next question comes from (John Coles) from (Cooperking). You may begin.

(John Coles): Hi. Thank you so much for putting this together. We're really excited about the Pre-Cert Program. I have been working with a range of startups as well as tons of roll out some products in health in this space.

And one of the challenges as I look through this that I wanted to ask about today was, how startups or early stage companies in this space can either work in companion with this Pre-Cert Program.

Or if we should start recommending the smaller companies that they actually incorporate a Pre-Cert process into their timeline given that they have yet to formalize some of the organizational requirements that you've outlined here. Thank you for your time

Bakul Patel: This is Bakul. Let me stretch from a couple of high level points. I think as far as considering whether startups or larger companies. I think you imply that the program is meant for all.

However, if you are recommending what folks should do I think our fundamental pre-mind from the program is people - startup companies should do what they should do that's best for their businesses, for patients, for making sure they are proactive for those five principles that I shared earlier.

It should be - we anticipated that that will exist in any excellent organization. So as long as you have a metrics driven or a vigorous excellent organization I think that's the setup we are looking for.

And I think those are the kinds of companies we would be expecting to sort of looking at what does good look like. And along next year we will be looking for those opportunities and looking for people even down the road how they get to that excellence and what do they mean by that.

Coordinator: Thank you, speakers. The next question comes from (Dan) from Bloomer Health Tech. Your line is now open.

(Dan): Hi everyone. Thanks for the update again this year. My question comes kind of around the selecting on the 2019 test approach and in more on what would come after the regulatory decision in terms of post market surveillance.

And how anything that happens there feeds back into the excellence appraisal and if say a company were to lose their excellence appraisal does that then impact all products that had been approved through this process? That's the first question.

The second one has to do with the pilot partners seeing as how a number of them have received approvals in the last year and a half or two. At what point do you transition to new companies to in a way not to pick winners through relationship with this process? Thank you.

Bakul Patel: Let me just - this is Bakul. Let me just share I think the intent of the pilot participants is for us to learn and inform the program and not necessarily about picking the nearest or otherwise.

I think where you started off of I think that what happens after the product is in the market. I think that's something that we continuously are evolving and I think when Marisa spoke about the real world performance part of the program is it has two big components.

There is the real world performance of the product perspective. And there is a real world performance from an organization perspective and that's going to need to continue for us to understand can the companies maintain their products. (Unintelligible) can the companies continuously maintain their excellence?

So again, imagine that feedback loop is really what we are trying to create. So if you read the working model you will see those components built into it.

I'm, not sure Marisa or Cisco if you have anything to add to that.

Marisa Cruz: This is Marisa Cruz. I think that you captured it Bakul. I think we are looking for post market data to as Bakul said ensure that products are safe and effective and also to provide continuous reassurance that companies are maintaining the excellence that was assessed during the excellence appraisal.

And so that will be a feedback loop certainly in this year in 2019 we envision that some of the real world performance both organizational and product level metrics will help us to further refine the Pre-Cert framework.

But then once the pilot is scaled, we envision continued data collection to be a mechanism by which we can work with pre-certified companies to pursue continuous improvement to ensure that excellence is maintained over time -- and to help support them in developing processes and procedures to do that.

Cisco, anything to add?

Cisco Vincenty: No. I think you captured that pretty well. I think the one point I would like to have all the people on the phone to kind of recall and remember it is this is not intended to be a compliance model. I presume that, you know, the fact that the metrics coming back and forth from market surveillance that means you are completely cut out and out of the excellence appraisal.

No. Your responsiveness to that, your behavior, your incorporation of that learning and your adjustment to that issue actually promotes an increase in your behaviors.

That's really what we are looking to drive. That's why the program is envisioned to be this continuous feedback cycle.

Coordinator: Thank you, speakers. The next question comes from (Arnu Sharma) from Stamford University. Your line is now open.

(Arnu Sharma): Hi, yes. This is (Arnu) and I have a question. You mentioned about the quality and regulatory framework per KPLC and I'm wondering whether the relations

such as 21C Part 11 plays into it? And if it is - if the data is really different from what it had been in the past about the Part 11 implications with software in medical device?

Bakul Patel: I think the concept of or what is expressed in the intent of the relevancy of Part 11 is a little bit outside the scope of this program. And I say that for two reasons.

One is, Part 11 was specifically intended for making sure the documents and the information that's collected and integrity of the documents and the data that's collected is maintained either during a trial, either during maintain quality or other parts. And that is why I say it's outside the scope of this program.

I think it's more about - this program is a lot more about taking into account how an organization is geared up or has the capacity to deliver products on an ongoing basis with high quality and has that same mechanism to react and correct issues in a proactive way.

Coordinator: Thank you. The next question comes from Mr. (Roy) from (Brains Corp). Your line is now open.

(Roy): Hello, everybody. Thank you for putting on this update. I have a two-part question. One is, something that you've clarified in the past that you are still in the process of figuring out the exact metrics that you would be looking for. One thing I'm interested to ask here is if that's going to have parallels with the CMMI sort of level? That's the first part.

The second part is, you know, so much of everything going on in regulatory nowadays is the emphasis on global harmonization so I'm curious if any of

your other partners in IMDRF are pursuing similar processes or if they are a part of this pilot itself?

Bakul Patel: Thank you for that question. I mean from a harmonization perspective where we are taking the harmonization that we had done or convergence that we have done in the framework is really where we are going.

Other partners across the world have been as curious as we are in learning what this program is shaping up to be and that's something that - that's something that we would take back to the regulatory form to determine if there needs to be an approach for moving forward.

Coordinator: Thank you. Once again, if you would like to ask a question please press star 1 and record your name and your company. One moment for additional questions.

The next question comes from Agata Anthony from GE Healthcare. Your line is now open.

Agata Anthony: Hi. I wanted to follow up on some of the questions that were asked previously regarding the regulatory authority. I was looking at the working model 1.0 and at the test plan. I have noticed that the test plan is designed to look at the streamlined review portion. There is nothing addressing the no review part for lower risk devices for L2 Pre-Certified companies.

I'm wondering if that is still the plan for Pre-Cert and if so does FDA believe that they would need additional regulatory authority in order to make that happen?

Bakul Patel: Thank you Agata for that question. It was by purpose we decided to use the De Novo pathway and to explore what could yield from an assurance perspective so we may or we may not need to review this. So I think that still is the intent of the program to explore.

However, at this particular time we want to make sure that we take into account all the components of the program itself and test them out before we can decide when certain parts or portions of the program don't need to sort of engage.

And so I think the intent here was to engage all acting parts of the program that we are envisioning and test them out.

Coordinator: Thank you speakers. Once again if you would like to ask a question please press star 1 and record your name and company. One moment for additional questions.

Our next question comes from (Jeff) (unintelligible) assistance. Sir, you may begin.

(Jeff): Hello. Yes. I have a couple of questions actually. One is, if the De Novo pathway is how the Pre-cert Program is going to be triggered how (unintelligible) the Pre-Cert Program it sounds like the FDA selector is something that the companies will have to express interest in.

And the other question I had is more about, how will - I'm trying to - I'm having a hard time picturing how the excellence appraisal will be conducted. Like what are the steps and maybe not in detail but in a general sense how will that work? Thank you.

Cisco Vincenty: So I think I will start - this is Cisco Vincenty with the excellence appraisal portion of that question and then turn it over to Bakul for the first question there.

But with regard to the excellence appraisal right now what we are intentioning for the 2019 timeframe is we will have a group of FDA participants the ones we've got right skill sets for to actually either attend onsite at the location of the company based off of where they have defined (unintelligible).

So there is a lot of pre-work that will happen ahead of time but it will be onsite. We will be willing to just engage with the company to go through exactly how the work is being performed with regards to those elements and domains that we've called out.

How they align to the excellence principles and that will be brought back in and then you would be able to say, okay, here is what they do really well -- and how does that translate into the portion of the review that we can streamline in some case in 2019 to test out?

So it really is going to be a much more interactive dialogue. There is not going to be a surprise inspection that happens. It is really intended to be as efficient and proactive as possible but we really are looking to move past just an SOP review and a compliance review.

It is truly geared at how are you actually performing the work and how are you measuring that work.

Coordinator: Thank you, speakers. Once again, if you would like to ask a question please press star one and record your name and company. Please limit yourself to one

question to allow other speakers to have their questions answered. Thank you.
One moment for additional questions.

The next question comes from (Zack) from AdvaMed. You may begin.

(Zack): Hi, thanks. This is (Zack) at AdvaMed. Thanks to the FDA team for hosting today's Webinar. My question was actually asked already by (Danny) which related to what we can expect throughout the pilot phase this year in terms of updates from the agency. So thanks for already answering that.

Bakul Patel: Thank you (Zack).

Coordinator: The next question comes from (David Richter) from Cambridge Consultant. You may begin.

(David Richter): Thank you. This is in relationship to Apple who is obviously a member of the pilot program and what their participation involves. So on September 12 they announced the Apple Watch 4, on the same day the FDA made an announcement about its capabilities and on September 11 the day before the FDA cleared the device.

So could you comment on the impact of being in the pilot program events in particular and just in general?

What are the advantages for a participant for being in this pilot program because there are advantages for being that relationship? So I'm wondering short term what the impact of being in this program is? Thank you.

Bakul Patel: So I'll - this is Bakul I will talk to that. I won't talk about exactly what Apple and particular companies. Let me just give you the opportunity the lifetime for

anybody including the pilot participants and the FDA is to learn from each other to build this program.

Now what we have not done so far is use the pilot program to clear or approve a product. However, what we are learning from this process is where we can be more efficient. Where we can sort of understand what happens in the company, what happens in the process and that's the impact for folks who are helping identify those things.

So I encourage everybody not just the people in the pilot participant who are informing us how products are being made and it's a learning opportunity more for the FDA than anything else.

But I would encourage everybody else to sort of throw out that same input so that we can build a program in the most efficient way that is closest to how products are being made.

Coordinator: Thank you. The next question comes (Peggy McLaughlin) from TMP Advisors. Your line is open.

(Peggy McLaughlin): Good morning, Bakul. That was exactly my question actually. Should participants expect the same proceeds clearance time? So I think you have addressed it. Thank you.

Bakul Patel: Thank you.

Coordinator: The next question comes from (Patricia) from BEIA. Your line is open.

(Patricia): Thanks very much for the opportunity. Sop within section 9 of the updated model you have clarified that a decision tree or a support tool is currently under development.

Could that help organizations draw linkages between the IMGRF framework and FDA jurisdictional elements with regard to classification meeting the definition for software function enforcement, enforcement, risk characterization et cetera?

As you already know such tool would drive enhance understanding of FDA's current thinking beyond the Pre-Cert and I was just wondering if you have a timeframe in mind for the release of that tool or further information.

Bakul Patel: No we don't. I cannot definitely point out exactly when we will develop and build. I think the indication in the working model is about building that tool. I think we are saying that the concept that was articulated on their framework required a method and a tool beyond just what was written down on paper.

And we are looking at ways again back to efficiency and back to the sort of ease of and experience for how folks could use the contents of the FDA categorizations and use it for that. So we are looking at ways to do that.

And again back to my request earlier I think if you have ideas on how to make that tool this is exactly what we will be looking for.

Coordinator: The next question comes from (Ted Pears) from Philips. Your line is now open.

(Ted Pears): Hello. Thanks for taking my question. One thing kind of jumped out at me when I was taking a look at the IMDRF and taking a look at treatment to

diagnose. And something that was noticed was in the IMDRF document it seems to talk about timeliness and temporal aspects.

Treatment and diagnose to describe IMDRF to take immediate or near term action and critical situation or condition talks about accurate and or timely diagnosis. And I wasn't seeing these references to time in 1.0 and so I don't know if that was intentional or am I reading too much into it? Thank you.

Bakul Patel: I think on Page 28 I think those points are captured where we have a table on IMDRF is exactly what it is - is we are looking at the criticality of a situation. Again specifically on the IMDRF framework we can tell that concept of timeliness is not necessarily a one dimensional aspect. It is multidimensional in collection and accumulation of other aspects and then timeliness becomes important.

What was expressed in the IMDRF framework - I think what we are looking at is in collective risk of the context of use is really what that criticality in this healthcare situation was identified. So I think that concept still exists and it is not missing.

Coordinator: Thank you. The next question comes from Mr. (Davis) from NeuroVision Imaging you may begin.

(Davis): Hi, thank you. My question is with regards to startups. In a startup environment we typically don't have a full set of records and you certainly don't have a track record. So I'm wondering how the assessment process would work for a startup and whether there really is a potential pathway with a Pre-Cert program for startups. Thank you.

Bakul Patel: Thanks for the question. I think as you can imagine and what Cisco mentioned earlier we are focusing our efforts on outcomes of the processes which also means that the knowledge of folks or employees in organizations about those processes are.

And records and documentation are two different aspects. The way I think about records and documentation - documentation is a way of letting people know what the process is and records can be imagined as results or outcomes of those documented processes.

Now, you could have those two take many shapes and I'm sure startups and mature companies or large corporations have that. What we are trying to do in this program is start identifying what types of records, what types of documentation, what types of outcomes we can rely on. Rather than imagining a document is a paper document or a Word document or things that are written down.

Coordinator: Thank you speakers. The next question comes from (Nadine) from PD Health. You may begin.

(Nadine): Hi. Thanks for doing this. I just have quick questions and some of them might have been answered already. So we were really disappointed to see that all the pilot groups were chosen - that were chosen were large established multimillion, billion dollar corporations with large budgets. And our concern is that the processes are being designed around companies that have hundreds of thousands of dollars or have millions to spend on the certification.

In our view it would be better to show a design process that works for the lowest common denominator for small companies trying to work in this space

and doing significant work but don't have multimillion dollar or billion dollar budgets.

Bakul Patel: Actually, I was just engaged...

((Crosstalk))

(Nadine): ...(unintelligible) address that.

Bakul Patel: That's a great point you've raised. And let me just underscore the choice of the participants as not just large companies. If you look at the mixed status that is in the 9 product participants is a measure and a range from not for profit with very small teams, two is really large organizations and some cross continents.

So I think it's an unfair view of how the pilot participant's mixture is. In fact we are looking at ways to not just look at large corporations but also small corporations and products. And so I would recommend look at the profiles of the people that are in the pilot participants starting with (Takepool) and onwards.

Coordinator: Thank you. It looks like we have five other questions in the queue. The next one is going to come from (Monica Harrison) from GE Health. You may gin.

(Monica Harrison): Good afternoon. Thank you. So I understand that this is certainly part of the pilot and all the testing phase that you are going to be working through. Given that it's one of the key benefits, I'm just wondering if you can share whether the team has sort of an initial goal or target you are working towards for the time for the streamline reviews.

I don't know if there is even an initiate target that you are working towards again, understanding you'll be learning a lot through the testing phase. Anything you can share?

Bakul Patel: Sure. Again, I don't have a number to share with you today but we are looking at minimizing effort on reviewers that would go into reviewing the product. And if you look the trajectory we are trying to head towards a place where the amount of time where reviewers spend at FDA to understand the products.

To understand how it was brought about and to understand how it was built is really trying to spread that knowledge or get that information in the excellence appraisal or in real world performance ahead of time so there is certainty. So our focus is towards minimizing the time and that is where we are focusing toward.

Now, where that number may land is something that we are going to learn but we are actually very cognoscente that if that number was very small it actually will benefit not just us but also for the industry.

Coordinator: Thank you. The next question comes from (David) from Insight Health Policy. You may begin.

(David): Hi, everybody. Thank you so much for hosting this Webinar. It's been very, very helpful. My question has to do with a letter that the Democrats sent to the FDA back in October about Pre-Cert along with a set of questions about the program.

I was just wondering if you guys have any updates on where FDA's response to the letter is and do you think we'll a response in the next few months or over the course of the year? Thank you so much.

Bakul Patel: Yes. Unfortunately I won't be able to share that information of that request back from the Senate and that's something that we will confirm with the folks who had requested that information and we will go from there as our processes allow us to give.

Coordinator: Thank you. It looks like we have three other questions in the queue. The next one comes (Caroline) from Comply. You may begin.

(Caroline): Hello. Thank you for hosting this. Very useful. I'm working from Europe and I'm looking for startups so far as medical devices and their customers are international companies that also work in the United States.

I'm really interested in how small companies with an ecosystem of several software of medical devices including corporate and hospitals and (unintelligible). How can they apply for a Pre-Cert Program in the future and can we work a little bit together so that in Europe we have the same dynamic real time audit system as in the States?

Bakul Patel: Great question. I will have to be very honest with you. We haven't thought that far but the intent is that we will all converge from an international perspective. I'm pretty certain a lot of folks are looking at what we learn from here that can be reused.

Of course other countries have their own jurisdictions and their own laws so that tethering will need to happen but here we are trying to lead and determine what's the best tailored way for this space in digital health and software in medical devices can be imagined and developed and to be expanded or used by other agencies.

Irene Aihie: We'll take our next question.

Coordinator: Thank you. The next question comes from (Jacob Graham) in (John). You may begin.

(Jacob Graham): Hi, Bakul. Actually it's (Jacob Graham). Good afternoon. Thank you and your team for hosting this Webinar. My question is about the future automation that was briefly mentioned in the 1.0 model to tap in to company metrics as part of the appraisal process and in the ongoing reporting of real world performance and analytics?

How should companies engage FDA in discussing details of that topic particularly those who can facilitate access to that data? Thank you.

Bakul Patel: We would be very interested and engaging. And thank you (Jacob) for raising that and giving others the idea on how to do that. That's one of our highest and the most interest area for us to sort of engage with you in that data collection, the type of data collection, the analysis and the signals that come - that could potential come to us and what it should be.

So we are very much interested. The team is very interested in learning and perhaps even experimenting with folks who have spent in this area and help us build that robust system.

Please email - I mean, you can email me directly or you can email the Pre-Cert inbox if you specifically have questions or suggestions on ways to engage with this.

Coordinator: Thank you. Our last question comes from (Anthony Watson) Canopy. Your line is open.

(Anthony Watson): Thank you. My question is really one having to do with I guess you would call it level of effort. And really what's trying to understand is, if you have other medical devices in your scope when FDA comes in and looks at those in addition to the software pre-certification.

Does FDA look at those as firewall from each other or is there some idea of leveraging because, you know, if the same assets are coming and the same people coming in to do the inspections is there going to be any overlap? Have you thought about that?

Bakul Patel: Yes. Thanks (Anthony). We have - I think you asked multiple things in there. I think leveraging definitely we want to leverage other standard views or other information that had already been collected. We haven't thought exactly where and how form the maybe use of that information. But from day 1 we have been - if you have a certification for cyber security from other organization we would be interested in seeing what we can leverage from that.

What we are thinking about the excellence appraisal activity is for folks as we said in our working model for folks to identify where the boundaries of their organizations they want to draw. And that could be kind of what you are insinuating with the firewall aspect but really they are allowing folks to say, for a software medical device products to go through this organization and the organizations can use, reuse corporate structures or not are build own processes.

But that boundary that could potentially cross across individual business units to corporate processes that boundary is something that we would want you guys to define and that's what we are going to pray -- because at the end of the day we want to make sure that boundary is really what we want to trust on

and can continuously continue to provide assurance for us to meet and delivery products and maintain products all the time.

Coordinator: Thank you. Once again if you would like to ask a question please press star 1 and then record your company name.

Bakul Patel: So it looks like we don't have any more questions on the line. I have to say I think these were some fantastic questions and its reflective of some of the things that we need to communicate better and we need to make sure that we're clear in how we are - the content we are providing as we move forward.

I will be very interested in hearing feedback and like I said before we welcome comments in the docket and we welcome comments and you can reach out to the email address we provided. It looks like we have questions.

Coordinator: Thank you. One moment as the name is gathered. We have a question from (Gabe Reed) from KTR Limited. You may begin.

(Gabe Reed): Hi, Bakul. My question is around Slide 15. I lost my connection earlier so if the questions has already been covered I apologize. It's about the sort of practicalities of how we get onto Slide 15 and so if I have a product that I want to put onto the market in the US. How do I contact you not with details but then what's the order of the process that takes place?

And also I know the excellence appraisal needs some further definition but I wonder if there is more of that (unintelligible) is going to be onsite for the submission process and have you thought about any non-US included in this process? Thanks.

Bakul Patel: Thanks (Gabe). Good to hear from you. Let me just share - I mean, one of the things that Cisco mentioned before was, we want to observe how products are being made. So one of the key principles I have asked the team to look at is how if the distributed teams it doesn't necessarily mean as the development of excellence of appraisal is happening they should be in one location.

So one of the concepts we are looking at is can this be done in a remote way? And that's one of the experimentation that will happen along the year to understand what does that look like and can we really do it understanding fully well there may be limitations and at the same time there may be opportunities to sort of do this and we may learn better things so that the appraisal may actually yield us the same kind of results.

And those are the things we will be looking for which could include the process of perhaps doing some pre-work - identifying what the boundaries are and then the appraisal itself or the process could be included to just looking and confirming some of those aspects that we are looking for. So that's one aspect.

I think you asked a question about how to get engaged in the lower part. I'm, not sure if that was the question. But like I said, I think we are looking to explore how we can get more test cases and portions of the test cases and experiments on - we could experiment on different aspects of the program and what we can learn.

The R on the screen represent the refinement and learning that we want to do along the way. So hopefully that helps clear up some of the questions that folks had.

Coordinator: Thank you. The next question comes from (Dan Zack) from Health Tech. Sir, you may begin.

(Dan Zack): Looking...

((Crosstalk))

(Dan Zack): Yes. Thank you for putting this presentation on today. Looking at the cost and benefits of the certification process the cost of participating is becoming more clear other than patient safety which has to already be the priority for companies that would participate.

Can you please help us understand the benefits of participation? For example, easier access to NIH, SDR, STTR grant funding and other grant funding opportunity to offset the hard cost of helping you design the program? Thank you.

Bakul Patel: Yes. Thank you for the question. I think the way we sort of framing the regulatory aspect of this program is purely on FDA side.

I think the funding aspects of this might be something that can come out and that may not be necessarily an FDA thing to consider. But it might actually be beneficial for others and we haven't thought through that and that's really not within the scope of our program at this time.

Now, I'm sure we will learn a lot, I'm sure we will be exploring other opportunities but I mean, funding opportunities in FDA program within NIH I think from a scientific - regulatory science perspective there may be some aspects that we could learn but not necessarily from a funding perspective.

Coordinator: Thank you. The next question comes from (Toni Herding) from Allscripts.
Your line is open.

(Toni Herding): Hi, good afternoon. Thanks for providing the update today. My question is around the generation of the KPI library that's mentioned in version 1 of the working model and what kind of status there may be on providing that and mechanisms for disseminating that to interested stakeholders. Thanks.

Bakul Patel: The - I would say that concept of creating KPI Library is still in the works and the mechanisms of disseminating it to stakeholders is also something that we are building.

What we are at this current time we are looking at is identifying those right KPIs that there is agreement those are the right KPIs that reflect and assures the continuous existence of a good process and the results of a good process is really what we are looking for.

As we saw in our working model we have about 12 or so domains that could have multiple KPIs and those KPIs once we learn is what we intend to build all the time. But right now at this time I think that the concept - the directional concept is we shouldn't have to reevaluate a KPI if it's not something that's normally used in the industry and that's reflective of what results or towards results and outcomes for certain processes.

So that's where we are going with this. Unfortunately we don't have that figured out and I'm not sure we will be doing that this year or at the end of it. But as the program matures and we collect more data points and this is why we are exploring ways to get more data points -- as we get more data points we will be much more informed of what that library is starting to shape up.

Definitely we intend to be as part of this program it should be transparent because we are now spending time or our resources trying to identify new things and at the same time letting the world know this what we have learned.

Coordinator: Thank you. It looks like we have two remaining questions in queue. The next one comes from (Nadine) from PD Health. Your line is open. Please ask your question (Nadine).

We'll move on to the next question. It comes from (John Coles) from (Cooper). Your line is open.

(John Coles): Hi, thank you for your time. I appreciate that a lot of the questions you are trying to figure out the timeframe right now and you are waiting on the February 8 deadline. I think my question is, do you have a sense for when we can expect a follow up timeframe for participation for clarity on some of these things so that we can plan our product development cycle moving forward?

Bakul Patel: I'm not quite sure. Maybe can you clarify when you said participation are you looking for product - can you clarify on that part because I'm not sure that I quite understood your question?

(John Coles): Sure. So I'm looking for a timeframe of when we can apply the program once it's broadened out or a timeframe when we would be able to submit products for review as part of this process even if we are not in the initial pool?

Bakul Patel: I can tell you what the scope of 2019 looks like for us at this time. I think the scope of 2019 is by the end of the year you are going to have enough confidence to see what path you want to go forward and how far and how big what the scope of this should look like in the coming year. But 2019 definitely I would say it's a test year for us. It's a test phase for this program.

Last year we spent time building conceptualizing and now we are in the process of saying, what practically works and that's exactly what we are doing.

So if you are looking for a product submission, I would recommend we get to the test phase first. Cisco, do you want to add something?

Cisco Vincenty: I think just to highlight - I mean, one of the things that I think Bakul mentioned is we are looking for additional test cases.

Now I don't know exactly what you've got in works or what you are planning but you know where to reach out through the digital health Pre-Cert mail box and I will provide a little bit more detail. I will request some time to discuss so that we can understand a little bit what exactly it is that you are thinking.

Coordinator: Thank you, speakers. Back to you.

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, February 15. 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 Webinar please complete a short 13 question survey about your FDA CDRH Webinar experience. The survey can be found at 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 for your participation. You may disconnect at this time. Speakers please (unintelligible) the conference.

END