

FDA- PreCertification (Pre-Cert) Pilot Update
Moderator: Irene Aihie
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Coordinator: Welcome and thank you for standing by. At this time all lines are in a listen-only mode. During the question and answer session please press Star 1 on your touchtone phone. I would also like to inform parties that today's conference is being recorded. If you have any objections you may disconnect at this time. Now I'd like to turn today's conference over to Miss Irene Aihie. Thank you ma'am you may begin.

Irene Aihie: Hello and welcome to today's FDA Webinar. I am Irene Aihie of CDRHs Office of Communication and Education. On July 27th the FDA announced the launch of the Digital Health 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 introduction.

This is the first in a series of Webinars 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, will present a model for demonstrating a culture of organizational excellence that was discussed with the pilot

participants during their kickoff meeting. Following Bakul's presentation we will open the lines for your questions related to information provided through this 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. Welcome everybody to the Webinar and this is a status update as Irene mentioned. In an effort to be very transparent through this collaboratively creation of the pilot program I want to start off by saying one of the things we heard very loud and clear as we engaged with the pilot participants is be clear. This pilot is not a typical pilot. We are actually developing the content of the pilot with the pilot participants.

So I wanted to share today what we shared with the pilot participants as a kickoff and early in the past month, we learned a few things and shared lessons learned and provide an opportunity for folks on the phone to ask questions about the program itself. Like I said it's a developing program for a pilot. And as we figure out, as we learn from the participants, we want to learn from you as well. So we welcome any input and feedback from you all as well and this is why we're holding this Webinar.

To give you a background on what we covered in the kickoff meeting with the pilot participants: We revisited and level set our goals and objectives. And I'll spend a little bit more time again even though we talked about it last time. We wanted to share where we were coming from and going to hear from them as well. And share how we are going to engage with the pilot participant and also look at questions we'll be asking to the pilot participants for learning how to do and develop software and maintain a high quality of software product.

And understand how they would consider excellence and those common perspectives we have shared before.

And I want to open that up afterwards and we did have a question and discussion and I will share some of those as well. But we welcome folks on the Webinar today to ask those questions of me as well.

So we did start off and just to reiterate we're looking at a program that is company based and moving away from a traditional model of a product base. How can we create a company based program that will lead to a streamlined regulatory approach for software and medical device that relies on culture of quality and organization excellence.

And we have shared our intent is to bring the trust and the technology. We need to bring the confidence in people making the technology. So how can we get there and how can we realign with the timelines that software is being developed, how do we align with practices people do and this is exactly what we're trying to learn is how do we learn those practices. And then finally looking at the software as a medical device principle that we have developed in the IMDRF framework we can align globally as well.

We've put this concept out there. It's important for us to walk through this again one time just to get on the same page. It's looking at creating a program that will certify companies and understand how to create software as a medical device, what excellent principles they use and trying to understand all those principles as part of the program. And then, you know, based on that excellence what products can be brought to markets right away and what products would be required of you.

We are in this process of understanding how this program can stay nimble and learning as well. This goes to the objectives and I'm going to spend a little bit more time here than other slides. And this is emblematic of what we did in the kickoff as well as the pilot discipline. I want to emphasize we want to create an efficient regulatory framework and efficiency's not just for, you know, industry or any one stakeholder. It's also for FDA. We are going to keep that in mind as we move forward we want to make sure us at FDA being more efficient ultimately allows products to be available to patients in a timely manner.

Having said that we want this pre-cert program to be easily maintained by all who are participating in this program. We want to rely on these excellence principles. We are focusing a lot more on excellence than trying to figure out whether we need to be very compliant or not.

Having said that using key performance indicators is really one of the concepts we are putting on the table for us to understand based on what people do or what we learn from participants, how can we sort of scale that to organizations of different sizes, different development strategies, aligning process freedom for people to develop software at the same time allowing those measures to be something that the companies or the organizations develop on their own. But at the same time can we get them to be aligned to those key principles that we all care about.

We want to scale this program for a variety of sizes of organization management processes they use today. And look in a holistic way of not keeping this program static and create something that will be out of the gate but also have the ability to sort of learn and adapt over time to make sure the program phase is current.

And with that most of you have seen this. And you've seen a lot of things that we have to do going forward as building the program. This is what I call our backlog of things to do in the program itself and what we want to do is we'll make this public. We'll make this list public and we'll see that things that we will start to solve as time goes on. And we'll encourage folks to help in building this, provide input along the way and be collaborative.

One thing I would say for sure that this is a unique way for us to co-create this with the stakeholders, all stakeholders, providers, industry manufacturers, software developers and other interested parties who can help us create this program that is best suited for patients at the end of the day. And we want to make sure that happens.

So we can do everything all at one time. So what we shared with the pilot participants is we started the pilot. We are going to take a focus approach. So in the initial part of this pilot program the next few months they're going to try to dive deep into this organization excellence piece. Where we are trying to learn is what does excellence really mean, how can we recognize it, how can we measure it in a way that's consistent, not looking at one we are measuring but also and going to my principles we've shared how can we sort of know people are doing the right thing, how do we find that trust, how do we know it happens in a way that we think is best for public health.

We want to be able to try to collect that information. We want to collect it. We will share with everybody and have a conversation largely with the entire stakeholder community in January. We are planning on having a public meeting at the end of January on January 30 and 31 so if people are listening save that date. We will be announcing that shortly but that's where we are going to take the learning that we have from the pilot participant and have a

larger discussion, dive deeper into what we need to do next and so on. So that's the space.

Going forward as we saw there's another big component of what the (unintelligible) view look like. How should we streamline that? What should that look like in terms of the roles for what a patient should do? What can be reviewed? How it can be reviewed so those questions will be asked in the next space. And, you know, along the same lines we will start looking at once we have a product in the market what's the real-world data collection look like. What kind of access we can get. What can we learn from that collectively not just as an FDA but as a stakeholder and how can we be more transparent about that.

So here's what we are doing as we do the site visits with each of the pilot participants. We have assigned five to seven team members to each of the pilot participants with one point of contact. (Marisa), (Cathy) and (John) who are part of my team are going to be the point of contacts for this pilot participant. How they're attending all the site visits with representation from premarket office, post market, compliance and we bring them on board.

The idea here is to have a diverse perspective as we look at excellence as people do it in their organization in their native form so we can learn from that and then present it to the larger community to sort of bring it back together and set the right bar where excellence should be. I would have to say that we are doing if you see on the previous slide in addition to the pilot participants we want engagement from everybody including folks, like, you on the phone today and others also. So we encourage that to happen.

A rough schedule and a plan that we shared with the pilot participants is we'll have the kickoff meeting. We'll start collecting information. We'll start

analyzing that information and we'll share that with the public as well and everybody who is interested in helping us. The asterisk as you see is something that we would start publishing on our Web site. You'll see those Web sites up there come up often on the pre-certification initial health Webpage. This is an opportunity for us to share publicly what we are seeing, what we would like to see and sitting in for some kind of participants and so on.

This is just another presentation for how we're pursuing the program but really comes down to collecting, aggregating, finding and then sharing publicly and getting broader input. Truly in the sense of co-creating the program and seeking input from everybody.

Let me share the model that we shared with the pilot participant. In order for us to understand excellence we put out these five principles is how do you provide safe patient experience, how does the organization look at quality and what's excellence in that perspective. What does sponsoring mean for an excellent organization? What does cybersecurity responsibility mean for an organization and then how do we assess that a company is truly proactive in its culture.

Taking these concepts we are asking folks to look at the description that we have and help us refine them. And we'll go over that in the next few slides but this is an excellent point. The model is if a leader of an organization would have its scorecard and have those excellence principles and has something that detracts how would they detract from people such as organizational and processors that they have in place. And balance it out or understand if those people in the organization that they have in place and the processes they have in place truly the results and an outcome from customer

responding back to those processes and people and organizations that they have. And how are they moving forward and learning and growing.

Again this is an initial model. We're looking to refine this over time. So you can completely expect this to either refine further or even change it from (unintelligible) base of input. And again this is not just with the nine participants. We encourage anybody who has input or feedback we recommend submitting your comments to the docket.

Here's what we want to see happen is taking those five principles, looking at the different perspectives. If we could sort of identify key performance indicators and a library of those and the best practices that can happen and that could get standardized over time. But being able to recognize those connections that people do in terms of processes and measures and how do they align to those is really what they're looking for.

Now this is a completely different approach than what's been employed in evaluating certain organizations. But allowing this freedom is really what the intention is. How we get there is something that we really need help from and we are hoping to learn that with the pilot participants and help us get to the next level.

Here's how we are looking and this is what we shared with the pilot participants to take that concept which I just shared in a couple slides ago is if we take one of those excellence principles and starting with patient safety what question would you ask of an organization or another organization not yours and what indicators or performance indicators would you want to see that aligns from an organization perspective and a profit perspective that lines up to the patient's safety.

So we provided a list of questions as examples, as guiding questions for people to provide input to or at least have the thought process going forward. And you can see there's other slides that talk about each one of those principles and have different questions answered then. Granted we had to clear up that there is a lot of duplication or sort of overlap in the questions you ask. But there is a purpose to make sure that we can ask the right questions in different ways that can really identify an organization that's excellent.

So skipping to some of the slides what we asked the pilot participants is how would you refine these excellence principles and just common validating perspectives of an organization that you think is excellent. And how do you think a person or an organization other than you can demonstrate that to a third party or to your leadership in your organization. And how can we look at an organization that is using metrics to evaluate performance of this excellence itself.

So we're looking for this very broad, very high level for feedback and trying to learn these things as we move to the site visit. We made it really clear that the site visits are not audit per inspection. It's truly to understand current practices that are used in these organizations and this is the reason why we picked the spread we picked and is to understand different perspectives both large and small and the type of industry they come from to understand how excellence can really reflect into the model that we are looking to build.

So here's what we're specifically asking which is asking folks to do. And this reflects some of the feedback during the conversation we had with the kickoff with the pilot participants is we're specifically asking people to modify the descriptions of the excellence principles, identify other principles that they think may have been missing or should be included. And also defining,

maybe refining common values and perspectives and just giving them an understanding of that.

The second big thing that we found was important for us to clear and as we sought input from the nine participants or learned from the nine participants was how can the processes that folks measure or use and measure align to their business needs. And I want to emphasize to their business needs rather than the traditional regulatory approach.

What I mean by that is we didn't want to collect input that showed processes that are aligned to their current, you know, CFR regs or something, like, that. But rather to why is it important to them to maintain, to have the processes, why is it important to them for measuring those things in their organization. So truly back to why people or understanding why they do what they do. And then taking those things and asking those questions and mapping them to that excellence and put into perspective what we're looking to get to sort of get to.

Understandably we also learned – I can share with you we have done three site visits so far. And we've learned phenomenal, great things from all of the three site visits. So what can out to be really clear is we had to be very explicit in terms of asking what we are asking and what's said in the slide. But also taking and effort from going to what they do in day to day life in their organization and then translating it to something that can be generalizable for their intent and objective of tailoring it to all types of organizations.

So that work is going to happen next but we ask and learn from the engagements that we have so far is that higher level abstraction is more important. But to understand that abstraction we needed to know what people do today. So this was an iterative process as you can imagine. We didn't

have a great answer to begin with or to take questions. We are iterating even on the questions. So I would hope as you guys think through these and have questions that you may want to ask that we can clarify and help us, like, shape those questions so we can get to those objectives that we will want to see sort of ultimately be established.

We shared this spreadsheet. We asked folks to fill out this spreadsheet with what questions would you ask in your organization that aligns the patient's safety from a resource and organization perspective and why do you ask that? What is the value-added questions that you ask your own organization and in relation to that what are the key performance indicators?

Now you can take the spreadsheet and start filling from left to right or you could start from recognizing key performance indicators that you think are important from public health and a patient's safety perspective and then ask the question why do we have those measures, what questions are you answering based on those measures and how does it line up?

This was a structure that we gave people to sort of complete and we got good input back and we're trying to compile some of the questions. We also before I move off that I also wanted to share that we gave in the spreadsheet which is also available for everybody to download is another tab which shows some example questions that FDA and staff here brainstormed to see what questions we would ask. And I would encourage everybody to use those as guiding questions but not necessarily answering those questions themselves but use them as guiding questions to complete this spreadsheet that we asked people to do.

Now I can imagine as you look at in your own organizations may have some of the components, may not have some of the components. But at the end of

the day if we get more input and it helps us and get that feedback from the nine pilot participants and from others the program model can actually be much more robust and that's what we're encouraging here. And that's how I'm trying to share that work with you and everybody on this phone.

We are inviting input from all stakeholders. Here's what we're doing. We are going to provide regular status updates on our Web site and you'll see that first iteration already on the Web site. We are going to have, like, Irene said in the beginning this is the first of the series of Webinars we are going to have along the pilot program. We are also holding the first public meeting at the end of January. I would emphasize save that date. It's going to be an important working meeting. We plan on working in this meeting rather than just talking. We will actually try to solve problems together and we invite everybody to do that.

We will request everybody to submit their comments and input to the docket so we can take that and use that information to build a really robust program. What we want everybody and all the stakeholders to do we encourage associations, trade associations or other associations, coalitions, alliances and other common interest groups to form and reach out to those parties who are interested and collectively build the input and provide it to the docket. I think we are looking to as broad of input as possible from everybody and to inform this building of this program.

We encourage groups to monitor our Webpage. We also want groups to stay engaged. We also want everybody to participate in this Webinar and in this public meeting. I think this is the best way we as a community can co-create this program that is best for the patient. So keeping that notion in mind - a patient we should make sure that we have the input. We as collectively FDA and all stakeholders have the input to create this program.

So with that if you have questions about the program itself, about the pre-cert program itself feel free to reach out to pre cert. If you have questions about what we're asking or anything on the Web site we encourage you to ask the questions to the pre-cert pilot, the email address. If it's anything outside of that feel free to reach out to (Dice) or the visual health email box that you already know. We will be recording this Webinar and posting the recording as well as the transcript going forward on the Webpage that you see here.

Having said that I'm going to open it up for questions and this is the time for you to ask question about the program, how we are engaging with the pilot participants, what questions you would have individually that would help us provide that input we'd be happy, I would be happy to answer those questions.

Irene Aihie: Operator do we have any questions?

Coordinator: We will now begin the question and answer session. If you'd like to ask a question please press Star 1. Please unmute your phone and record your name clearly when prompted. Your name is required to introduce your question. To withdraw your request press Star 2. One moment please for your first question.

Bakul Patel: So while people are queueing up for the question I'll just throw out something that we learned on the site visits and interacting with the pilot participants. One of the things that we had to clear up with the pilot participants is how would you ask the question of others that we are asking of you is a good way to think about how to approach providing feedback.

One example that came up was, like, if folks are evaluating their vendors what mechanisms do you use to evaluate your vendors, what questions, what key excellence questions you're looking, what principles you're looking for those

vendors. Again for the purpose of your business might be to get the great product out but from an overall high level perspective how would you think about asking that question of your vendors for picking the right partner with your organization. So thinking about that is something that we discovered was really useful to talk through.

Irene Aihie: We'll take our first question.

Coordinator: Your first question comes from (David Amore). Your line is open.

(David Amore): Hey Bakul. Thanks again to you and your team, Cathy and everybody else for a really excellent and collaborative session to speak with, so it was a fantastic opportunity to collaborate with you folks. And I mean it's really an important effort of developing this new digital health framework.

So that being said I think one of the things that I wanted to ask generally here today is as we and the industry go through this program would you say it's more important that we think about how companies today currently meet the existing regulatory framework or more generally how they instill confidence in healthcare providers, payers, users, patients and other stakeholders in our company, some products by really demonstrating that excellent software development practice as an organization holistically?

Bakul Patel: I would say the latter (David). I think that's a great point. It's less about the existing regulatory framework. It's more about what's the business doing best for making sure they're delivering the right product in the right way with the right excellence. And that's really – and the excellence can be not just only for FDA purposes but also, like, you said it's about for the stakeholders we care about in the ecosystem is the payers, the providers, the patients included,

right? So it's about being how can their excellence recognize that everybody in this healthcare ecosystem.

(David Amore): Great thank you.

Bakul Patel: Thank you.

Coordinator: Your next question comes from (Arina Angel). Your line is open.

(Arina Angel): Hi thank you so much for the excellent presentation. I have a question from the perspective of real world provider in this position, like, (unintelligible). And my question is (unintelligible) engage or (unintelligible) work with providers either by (unintelligible) a couple of (unintelligible) ask in addition (unintelligible) communication that have (unintelligible) physicians aren't able (unintelligible) and maintain relationship. And, you know, (unintelligible) in a different way that data (unintelligible)...

Bakul Patel: Can I just pause you for a sec. We could hear only every other syllable. You're cutting out so would you be able to repeat your question or get a different connection?

(Arina Angel): I will try to get a different connection. I apologize and I will try to maybe submit it in writing. I have another participant to have an opportunity.

Bakul Patel: So you're better now so before you were not. So if you want to ask quickly a question before your line gets...

(Arina Angel): Okay. Sorry for the confusion. I had a question if there's any plan or possibly to engage individual providers who are not a part of an industry or academia who have a source of data, hard to reach patients. Say agoraphobia patients

and also could provide an insight to improve precision in caring to some type of patients with mobile devices to interpret this data to look at them.

Bakul Patel: Yes this maybe I'll just answer what I understood. I think you're asking is there a way for individual patients and providers to share information that can lead to better outcome. I'm hoping that's your question.

(Arina Angel): No. Sorry I will submit it in writing. I apologize for the connection.

Bakul Patel: Yes please do.

(Arina Angel): Thank you.

Irene Aihie: We'll take our next question.

Coordinator: (Susan Sheldon) your line is open.

(Susan Sheldon): Hi thank you for the excellent presentation. I was wondering how did you select your initial participants for this pilot program and if there is room for other people to participate at this point?

Bakul Patel: So first of all I think I would say that this program is a development program developing – you're working with the nine participants to develop this program. And the thought process we went through a public process. We asked for people to submit their names and interest in participating. And we eventually selected the process and fundamentally I'll just summarize the selection process into one sentence. With the goal of developing this program together with the nine participants and all stakeholders they're looking to learn the most from each of the nine pilot participants. And this is how you

can see the spread and the diversity in the types of participants we selected and that was the thinking and rationale behind the selections.

(Susan Sheldon): Okay thanks.

Bakul Patel: Okay.

Coordinator: Your next question comes from (Timothy Holick). Your line is open.

(Timothy Holick): Hi can you hear me okay?

Bakul Patel: Yes.

(Timothy Holick): Okay great. I was just curious about the public meetings you said you were going to be trying to work specific topics and work through comments. Does this Webinar kind of go by the announcement and for the patient for that or could we expect more detail about what you'd like submitted for discussion or work there?

Bakul Patel: Oh what I said in this Webinar was purely a save the date. There will be a formal announcement. And there will be much more detail published. We are still formulating the agenda, etc and we'll look for – and again it will be informed by the interactions we have and the next level of questions as we're uncovering and learning through this pilot program. So there will be a lot more details to be coming. So if you have thoughts there will be opportunity and an avenue for you to provide that as well.

Man: Okay great. Is it okay if I ask a more substantive question too or should I just requeue up in the question?

Bakul Patel: If it's about the public Webinar so you can send your emails to FDA-precert pilot and we'll get to you. If there is anything specific that what I presented today I would be happy to answer.

Man: Sure. Yes I just wanted to ask so far with your kickoff meetings – without getting into specifics have you kind of encountered the collaborative spirit you seem to be aiming for with the announcement or do - or are people still seem to kind of hold things close to the chest when discussing with the FDA?

Bakul Patel: I can tell you without hesitation I think the eagerness to share, eagerness to help in creating and building this program has been phenomenal. I've been completely humbled by the eagerness and the willingness for people to help build this program in the right way. So I would say it far exceeds, you know, anybody's expectation in how open and willing this - the nine participant - the three we have visited so far and to the kickoff we have heard everybody willing to co-create this program with us.

Man: That's great. Thanks for your time.

Bakul Patel: Thank you.

Coordinator: Next question comes from (Karen Keely). Your line is open.

(Karen Keely): Hi there. It's (Karen Keely). I'm a biotech consultant. Can you hear me okay?

Bakul Patel: Yes.

(Karen Keely): Hi. Thank you for all the information. It's been very informative. I do have an ecosystem question. I work a lot with rare and orphan diseases, clinical trials and also in the autism community. Down the road are you hoping to focus

these devices in the healthcare ecosystem on any of those groups because I can say that that would be extremely needed and very beneficial?

Bakul Patel: Absolutely. I think as you can – as you saw we didn't pick any specific disease type with this program.

(Karen Keely): Right.

Bakul Patel: This program is supposed to be very agnostic. What we are trying to create here is an extremely efficient and streamlined regulatory program that can get to those disease types and those areas of public health that need most attention. We are trying to get innovation and happen in the space in a way that...

(Karen Keely): Right.

Bakul Patel: ...reaches patients that we care about. I think that's exactly the intent behind this so your question is spot on from that perspective.

(Karen Keely): Oh I'll be following it closely because it's very interesting. Thank you so much.

Bakul Patel: I would encourage you to attribute as well as follow.

(Karen Keely): I will absolutely. You'll be hearing from me. Thank you.

Bakul Patel: Thank you.

Coordinator: Your next question comes from (Jeff Met). Your line is open.

(Jeff Met): Good afternoon. Can you hear me?

Bakul Patel: Yes.

(Jeff Met): Excellent. Well thank you for the Webinar and for the information. As it relates to the KPIs can you say whether you are looking to leverage industry standards for software development such as those meant for quality management or risk management as part of this pilot? And specifically I know that the Association for the Advancement of Medical Instrumentation AAMI is working on set standards for health IT software. And I'm just curious to know if you're looking to leverage those kinds of standards as part of this work?

Bakul Patel: So standards we would leverage anything and anything that's relevant in keeping organization excellence. That would be my short answer. But I would say yes is those standards are followed within our organization is those - and some that reflect - is reflected in either certification or other way. We are actually taking a very broader holistic look at an organization other - outside of in the (call your) systems regulations - I'll call it the systems or just risk management. We are looking at how an organization truly excels in making sure to provide safe, efficient experience and maintaining high product quality and so on and so forth as we highlighted in those excellence reports.

(Jeff Met): Okay thank you.

Coordinator: Your next question comes from (Gesa Rau). Your line is open.

(Gesa Rau): Hi. Thank you. Good to hear from you (Bicole). Thank you very much for a great presentation and a very open invitation to participate. My question is a follow-up from the very first question you answered relating to focus of this

effort being more on the process and less on the product. And given however that digital health can include both hardware and software certainly we can't completely move away from the regulatory - existing regulatory processes as (proposed) - just the question just before this one. So I was wondering if you could comment on a perspective here that to the extent we have a precedent in the traditional medical device regulatory environment of contract manufacturers having to meet certain requirements and being certified in certain ways regardless of the actual product. And the concept there is that their process has been certified to meet certain requirements and therefore it allows certain low risk products to simply go straight to market as long as they work with certified contract manufacturers. Is that an analogy that you think would be applicable over here?

Bakul Patel: I think so we are looking at (early) in the concept is very similar. If we look at what we are trying to do is we can – we are trying to identify people who we can trust make good products in a way that can actually be health recognizable and drive towards excellence rather than just meeting a bar. And let me explain that right?

So if you can think about an organization that you're out for saying or you're getting services from or developing software if you are looking for an excellence in that organization the question is what excellence are you looking for and how does that excellent lineup to the patient safety and public health means? And that's what we're trying to get to. So if that - if it takes the concept that you just mentioned I think it applies but you're trying to deal even broader than that and apply to everybody who wants to do – who wants to bring products to the market in this space.

(Gesa Rau): Great. Thank you.

Coordinator: Your next question comes from (Pasello). Your line is open.

(Pasello Barlett): Yes hi. My name is (Passelo Barlett). First of all thank you very much for this great program and engaging the entire industry and stakeholders. My question is sort of stepping back from the specific program focused on the company. How are you all thinking about still ensuring efficacy of the actual product and the review process for efficacy and I think continuing to provide what sometimes is perceived by the industry and by patients is some validation that this stuff actually works because I don't see that really jumping off this process?

Bakul Patel: Yes great question. I think I'll actually expand on what you just asked. I think maybe even reading into where you're coming from. I think the intent of this program and definitely the objective of this program is to not change our need to have safe and effective products. I think in fact we are looking at a way where we can find the people who can do that evaluation. When we have one of the principles, referenced principals about being clinically responsible I think that speaks to the effectiveness of the product. The high quality product excellence principle leads to a safe product.

So as you think about those different principles that we highlighted as part of certifying or pre-certifying the organization that is baked into that - their concept. However I think like you mentioned we are not talking about, you know, lowering the bar on the 50 year effectiveness but rather looking at people doing all – anything – anybody who's making products or least in the virtual health space for this program in the space rather it's reviewed or not we're looking for folks and organizations who are actually good at doing those things.

(Pasello Barlett): So that you're looking to the third part certification to review the efficacy of the products that are submitted?

Bakul Patel: We are looking out the process that the companies follow to do and to make sure that people in the organization is doing their - so that's the certification part. And then if that today it requires us to review those projects we are looking at how best to review them. I think that's where the efficacy and the safety review can happen. But that's again risk based and also making sure that we have trust in those companies, making products that are even not being reviewed by FDA so that review part is still in the same paradigm and the concept that we have today.

(Pasello Barlett): Got it. Thank you.

Bakul Patel: Thank you.

Coordinator: The next question comes from (Steven Barnell). Your line is open.

(Steven Barnell): Hi (Bicole) and thank you to - for yourself (Kathy) and the team for a very collaborative meeting. So I would just like to emphasize the importance to - of building this together with industry and the approach you're taking. I think it deserves to be recognized the transparent approach you're taking both with the nine and with the broader community. One observation from the meeting this week and the process to date is, you know, this -- and it's obvious to everyone -- is no trivial task. And many of these measures can be quantified for some of the things around product quality and companies have many measures of clinical responsibility and product quality.

Others are much more subjective and qualitative if you like culture and how proactive you are. And I think one of the things that we really need to go wide

and if you like brainstorm with across the entire community is how we can really define measures for these more subjective or qualitative things. And I wondered if you could speak to that a little bit?

Bakul Patel: I'd love to and I thank you to you. And I think like you said I think some of us got – we do anticipate some of the measures will be qualitative. We also anticipate some of those measures will be (computative). I think some of the qualitative measures will have to be – any measures would have to have a balance sort of outcome measure that sort of shows that those qualitative measures do actually matter. For example you used the word culture and understanding a proactive culture may have a measure that may be purely qualitative but as a result of that qualitative measure is that – is the presence of proactiveness in an organization or a presence of high touch communication does that result at the end of the day in product quality? And how can we use proxies, how can we use measures that may not be necessarily direct but may be adjacent or may be a way to sort of indicate that being that particular aspect exists is really what we need to look for?

So I'll – I think as people do diligence for acquisition, people do diligence for vendor selection, people - things like Morningstar reports, things like Dunn & Bradstreet, stuff like evaluation those methods are - and culture evaluation that have – that there's a science and a field that sort of exists can we learn from those? And it's a great pointer about can we leverage those things that are already there in the capital industry, in other industries that we can use that to then identify objectively whether a company is truly excellent or not is really what we're after. So great point and I think we would welcome other thoughts, other things that people may have been doing in other areas, maybe not necessarily in this healthcare space but maybe other spaces, other sectors that we can bring sort of the sector would be phenomenal. And we encourage anybody who has input or ideas apart from on that that and we will take it.

(Steven Barnell): Thank you. I totally agree.

Bakul Patel: Thank you.

Coordinator: You next question comes from (Carl Washburn). Your line is open.

(Carl Washburn): Happy Friday and thank you for a fantastic Webinar. Even though we're not a partner in the pre-cert development program we are benefiting greatly from the thought leadership, the transparency and the openness that you're showing throughout the process including today's Webinar and the public meeting. So back to the point that (Steven) was making how often do you see the team presenting Webinars and is there any framework for broadening the discussion for those who are not pre-cert members who, you know, look into some of the discussions or discussion board or some other way to participate other than these Webinars which are fantastic?

Bakul Patel: So great question (Carl). I think so if your team is going (unintelligible) what is exactly what I am addressing. I'm encouraging caution the (lances) through the (unintelligible) group, encourage your group to sort of be on top of this, the discussion. And the discussion and the content we are looking at as we sort of learn more we are going to put – we are putting up on the Web. The spreadsheet I'm showing is already up there. So I would encourage you guys to look and follow what's happening in the preset program as we are building, as we are learning, as we're collecting information and whatever. I encourage every group to sort of come bring together their class and add to the inputs that we are seeking. And the docket mechanism is exactly what we want people to sort of provide that input towards. Engage us in asking what questions we're asking that we can clarify what we're asking to the pilot participants. If that (house) is helpful in you to provide input to us. So and

exactly to the point. We want everybody in this community to help us build this together.

(Carl Washburn): Thank you.

Bakul Patel: Maybe I didn't answer your one question about how frequent we're going to do this. So as you can see they're a little bit time constrained between now and the end of the year so probably have this only Webinar now and followed up with a public meeting or my or intent as Irene said in the beginning it's going to be – we're intending this Webinar is to be a series. So as we have more information we will periodically keep people updated in addition to putting content on the Web.

(Carl Washburn): Yes the point I want to make is even today's Webinar fantastic information you presented. But we're all benefiting from listening to each other's questions and so thank you for creating this forum to allow us to communicate with each other.

Bakul Patel: Absolutely.

Coordinator: Your next question comes from (Wallace White). Your line is open.

(Wallace White): Thank you. I'm curious to see how this will work out and how this program can be shaped well to work both for consumer product companies and for medical device companies. I know both of them are involved in the (path) which is good. For the medical device companies who are entering digital health but already have established processes to be compliant with QSARN ISO-1345 certified how will we make sure this doesn't become a whole second layer that they have to add to their processes that actually becomes more burdensome? And also related to that do you expect for the pre-cert

programmed to apply also to suppliers such as 1345 certification can apply to a design supplier?

Bakul Patel: Well I think you're making a really good point about, you know, what we are trying to achieve. And like I said in the beginning this is not about aligning to 1345 or not aligning to Phase 20. In fact we are on purpose asking people as we build the components of the program and the excellent principles and recognizing those is really going back to the right thing the companies do and organizations do for their business.

If we can identify those right business objectives and that alignment to those five principles I think the secondary question is how that sort of aligns to those other standards and requirements. And that is not something they're exploring right now. That's a task we will take down the road. But that's where we are going back to the base and the fundamental principle can we recognize an excellent organization?

Can we give people credit back to all the great things they're doing? How can we do that? And if there's something lacking how can we shine a light so people can fill those gaps? And that's really what they're looking for. I actually in the process forgot your second part of your question. Would you mind repeating it?

(Wallace White): Sure, whether the pre-cert program and a certification itself would extend to suppliers such as groups could do software development rather than strictly being to at least what I'll say is the equivalent of the manufacture record to the company that sells the product and takes on responsibility for its adverse events and so forth?

Bakul Patel: So I don't know if you are one of those people or not but I think there is...

(Wallace White): Yes.

Bakul Patel: ...is definitely an opportunity for us all in the entire, you know, chain of building products to get on the same page. And we are hoping this framework would enable us to get everybody in the entire chain be on the same page with the same principles. So we are all shooting from the same direction. So I'm hoping someday that these principles can be applied at the same level that a design house can also be – can also show that they're meeting. There's some inefficiencies in that process.

(Wallace White): Okay that makes sense. Thank you very much.

Bakul Patel: Thank you.

Coordinator: Your next question comes from Matt Trachtenberg. Your line is open.

Matt Trachtenberg: Hi (Bicole). This is Matt Trachtenberg with BD. I appreciate you sharing your - the spreadsheet. We have a different appraisal questions and I'll take a look at them. It seems like a majority of them are how questions, so how do you prioritize something? How do you become aware of an issue? And I'd like to better understand how you see us going from all those how questions which could have many different varied responses to these metrics and their KPIs?

Bakul Patel: So that's a great observation. You can tell that was Version 001 of the questions that we created and truly have to be used as a guiding set of questions. But I can tell you that you spotted something that we also – we're also trying to evolve and reiterate towards Nexus really asking the question do you have such and such process and why do you have it? If you measure something the question to ask is why does it matter and what value that

measure adds to your business. And then if it adds value to the business how does it line up or how does it align to the rational principles?

So I think reframing and learning working through that is something that we will end up evolving over time. And I guess the question I'm – I would ask back to you and everybody on the phone is how would you – how to frame the questions in the right way knowing that the intent we have and the objectives we have for as I'm creating this program how would you do that? And that's something that it would be greatly that for us to sort of understand is what resonates well? I think this is purely one way of looking at it if it but if you're hearing sort of what we want to achieve and measure we would love to hear feedback from folks is how should we be asking this question.

Matt Trachtenberg: Understood. Thank you.

Woman: We'll take our next question.

Coordinator: Your next question comes from (Garret Marin). Your line is open.

(Garret Marin): Hi. Thanks for the time to speak today and thanks for a great presentation. I have a question about we understand medical devices are not included in this present program. And specifically I'm in the insulin pump industry. So I'm curious what you think about the mobile applications and the software applications that connect with and interact with devices and how they might be included in the future?

Bakul Patel: We are starting small. I can be very honest with you. I think and to your point about an observation of medical devices not included that's not entirely true. We have two companies who are very medical device, traditional medical device companies that are in the product program. And I would also say there

are other organizations in the nine pilot programs and they're making medical device means they're - they may be making purely software as a medical device but that's where we're starting as a starting point. We are not talking about software in a medical device yet that could be down the road.

But we wanted to make sure that we had the scope right, we had the way to sort of paint it for this area first before we expand it to other areas. So and I - to be seen down the road but we wanted to make sure that we didn't expand too much that we don't achieve the goals of this program from the get-go. So it's really it's scoping and managing of the issue - the issue sort of approach we are taking.

(Garret Marin): Okay that extends to applications that interact with those medical devices but are on a separate device like a smart phone or a mobile app type thing. That is excluded as well at this time?

Bakul Patel: So currently we are focusing on when software becomes a medical device on its own. That's really what we're focusing on. So maybe you're referring to things that may not necessarily be that but they may be an accessory or something else to the current other medical devices. That's currently not the focus for us but we're looking at only software that can evolve, iterate and be developed extremely quickly using that as a baseline.

(Garret Marin): Got it. Thank you very much.

Bakul Patel: Thank you.

Coordinator: Your next question comes from (Nancy Stade). Your line is open.

(Nancy Stade): Hi there (Bakul). Thanks very much for the great presentation. So I'm hearing you describe a very broad program but I can think of a couple of ways the program could be challenged. And I hope you speak to just two of them. And the first is you alluded to earlier but I want to drill down a little bit. Consumer manufactures entering traditional device space. And I want to think about ways they might have difficulty establishing something like patient focus. So that's one whether you've seen that or whether you anticipate any unique kind of challenges there.

And then the second is, you know, what about novel technologies, technologies that may be less familiar to FDA in their traditional reviews such as things like machine learning or multi-analyzed algorithms? Do you anticipate any limits to who can benefit from the program based on novelty or complexity of the software product?

Bakul Patel: Great questions (Nancy). I think the first question is about folks who may be entering this space may not necessarily have all the components that we are highlighting as the excellent principles. But I - so if we take a step back what we're intending to do is with the nine participants understanding what those challenges would be. And perhaps you and folks like you can help us sort of figure out if people have those challenges what's the right way to those gaps that people can fill in?

Or the intent here is we inform people of their – of what is needed to create good high-quality product and how our organization can support that high-quality product that would be beneficial. So that's the intent behind highlighting and staying at this very high level excellence principal and highlighting what could be potentially be a gap for your organization who may not be similar or - and have them fill the gap as they may find it. So that's really what the intent of this – and hopefully you can build it with the

nine and others who are helping us build this together. And that's really what we're looking for.

The second part is I think we're making this – we are - since we are focusing clearly on software those novel technologies are ways those novel algorithms can develop it's completely included in this way of what - how we're approaching the program. So it's not pick off whether it's developed through machine learning, the algorithms develop the machine learning but then there are unique challenges that we still have to address in terms of what does clinical evaluation look like for those kind of products and how should we be evaluating. And those kind of – those questions will still be – they'll still exist and you still have to solve those. But where they're going is – going with this is that the organization knows what to do best for whatever the digital health technologies they're making. And then they have a way to show they have infrastructure and people, processes and show valuably that their meeting those five principles it would still be okay to be pre-certified. And you have to figure out what that means and how many levels we can have for a pre-certification, et cetera, so to be defined but the intent is to include those novel technologies as well.

(Nancy Staid): Thanks very much (Bakul).

Bakul Patel: Thank you (Nancy).

Coordinator: Your next question comes from (Jacob Lamb). Your line is open.

(Jacob Lamb): Hi, good afternoon. I think we all appreciate the proactive excellence principal in terms of quality of the product, effectiveness, post-market surveillance, et cetera. I'm curious whether the pilot participants raised particular concerns with FDA. And that is the fears companies have in being too proactive. I've

seen and lived that fear in when and how to ask users and patients for feedback. The fear isn't based on a worry of receiving very negative feedback. The fear is more resource based and whether the company would be prepared or paralyzed in following-up on anything and everything that could be construed as their product being deficient in anticipated performance.

So with the possibility of software devices now soliciting feedback from patients on a scale not previously possible I'm curious how or whether the agency thinks this may be addressed by the proactive principal that we'd like to instill?

Bakul Patel: Great question and I can tell you we haven't completely thought through that process yet. I think we're – what we are trying to get to is one of the constructs in this in this approach is we do want to be – we want people to be proactive. We want people to know what's happening. As you can see from our policies on cyber security and in terms of software we want people to sort of know what's happening before it happens so they can prevent further adverse conditions emerge. How do we sort of get there? I think that's a question.

Now what the regulatory paradigm would look afterwards after we all agree in the world of software you can learn a lot more and how do you leverage that? The question is when you know and you don't do - don't respond to those things in a proactive way what is the question that the company needs to have? In my mind I'll summarize this and say in my mind if somebody knows and has a good handle on understanding what is going on with their product you would expect an excellent organization to proactive and corrected and that's really what we're looking. Now there's of course a balance and we need to figure out what that balance is and that this is where I think as we get down deeper into understanding post market real-world data collection that would

be a discussion to be entertained. And I think that would be a good way to sort of figure out whether that one should be.

(Jacob Lamb): Thank you.

Bakul Patel: Thank you.

Woman: We'll take our next question.

Coordinator: The next question comes from (Wallace White). Your lines is open.

(Wallace White): Thank you again. Bakul, I think earlier you said in your presentation that you were aiming for excellence rather than meeting a bar which is an interesting and good point. I'm reminded a little bit of 20 years ago or so when I drove through Montana back when they didn't have a 55 mile-per-hour interstate limit and they posted signs up safe and reasonable or something like that. And it actually made me think when I drove is 55 miles per hour safe and reasonable for where I am right now? And in other places you could drive more faster. Are you implying there is that we need to better than people who've gone under CFRA20 in some cases do not simply meet the bar but truly seek out excellence in these kinds of devices and products?

Bakul Patel: The short answer is. I think and what I'll - I can tell you that I'm finding and I – and there's a hypothesis where folks are doing a lot more than what we're asking already. I think people are aspiring much harder much more than, you know, just simply meeting a standard of some kind. So I think in the world of software and that is – that evolves over time and we want to make sure that these products like typical software has to be updated.

And that's of course a lot of proactiveness, means a lot of collaboration. That needs a lot of vigilance. How do you sort of build that in and that's really what we're shooting for. So I think your analogy is perfect and exactly what we're looking.

(Wallace White): Okay thank you.

Bakul Patel: Thank you.

Coordinator: As a reminder to ask a question please press Star 1 and please record your name clearly when prompted. One moment please for the next question. And I am showing no further questions. I would like to call back over to Irene Aihie.

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 Thursday, November 30.

If you have additional questions about today's presentation please use the contact information provided at the end of the slide presentation. As always we appreciate your feedback. Following the conclusion of 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 Webinar. Again thank you for participating and this concludes today's Webinar.

Coordinator: Thank you for joining today's conference call. You may disconnect at this time.

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