

**FDA Webinar: Digital Health Software Precertification (PreCert) Pilot Program**  
**Moderator: Irene Aihie**  
**August 1, 2017**  
**1:00 pm T**

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 of today's call, you may press star followed by one to ask a question. Today's conference is being recorded. If you have any objections, you may disconnect at this time. And now, I'll turn the call over to Irene Aihie. You may begin.

Irene Aihie: I am Irene Aihie of CDRH's Office of Communications and Education. On July 27, the FDA announced additional health innovation action plan and the launch of the agency software pre-certification pilot program. The FDA recognizes that we need a regulatory framework that accommodates the distinctive nature of digital healthy technology, its clinical promise, its unique user interface, and the industry's compressed timelines for new product introductions.

The Digital Health Innovation Action Plan provides details and timelines for our integrated approach to digital healthy technology and the implementation of the 21st Century Cures Act. Today, Bakul Patel, Associate Director for Digital Health in CDRH will present an overview of both the Digital Health Innovation Action Plan and the Software Pre-Certification Pilot program.

Following Bakul's presentation, we will open the line for your questions related to the information provided through 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 thank you everybody for joining the webinar. I'm really excited to talk about the action plan and the pilot program, but before we do that, I want to cover three things today and I'll touch upon that briefly before we start. One is how we got here, all the work we have done so far, all the policies that we have put in place, and how we are adapting, and how we are taking that into consideration as we move forward.

Two is the details of the action plan of what we are going to do to align ourselves and meet the requirements of the law that we just got on 21st Century Cures. And most importantly, share with you the concept of the pre-certification idea or the paradigm we are trying to shift towards that will allow people with excellence in organization as well as culture of quality to advance and have products available to the patients in the U.S. with high quality. So how do we sort of do that and try out -- we are announcing the pilot program. We announced the pilot program last week to talk through how we can -- or learn how we can sort of best design the program with the help of the pilot participants.

So let me just take you through the slides here to talk briefly about how we got here. Most importantly, you all know the advances of the digitization that's happening is really affecting everybody across the spectrum and is really moving healthcare from the clinic to the patient. And as we sort of dive into how competing power sensors and connectivity, along with software, is really

changing how healthcare is being viewed is really important for FDA to take and allow these technologies to be available to the marketplace.

And the next few slides I'm going to share with you, it really talks about how we have been approaching these. We at CDRH care about patient centered healthcare. We also want to bring trust and innovative technologies to all the stakeholders in the healthcare, and finally, we do want to partner and our pilot program is an indication of how we want to partner with our customers, and using the word customers on purpose, they mean all stakeholders including patients, including providers, including caregivers, and developers who can get us to a digital future ready state.

When we think about how we are approaching our policies, we look at this risk based approach as a fundamental, which really takes us to this functionality focus, which means that we really are agnostic about how small or how big a product looks, but really focused on what the product does. It allows us to give and allows everybody to have independence from the technology that's being developed at a very fast pace. It also allows platforms to evolve over time and promote innovation in that area where technology is moving at a very, very fast pace.

The other part of our thinking has always been we want to be narrowly focused, which means we will continue to focus on higher risk technologies, but not necessarily focus on all technologies, which will allow us to sort of get to promoting patient engagement and protecting patient safety. So this is the paradigm we've been thinking since 2013 and we published several guidance, which sort of outlines our policy or thinking and looking at how we would approach from a digital health perspective and how they have now become foundational in what is considered higher risk and what is considered to be

lower risk, and taking a very pragmatic approach towards overseeing them with a very practical and an integrated approach.

This work was not done just unilaterally within the U.S. but we have also been leading efforts on the international front to create a framework with our international partners, regulators across the globe to come up with a framework for software as a medical device that actually will level set the approach that every regulator takes across the globe when such technologies are available to the patients.

So we have been working through that and they have also become foundational building blocks for how we will approach and how we are thinking about it. So taking another step from a different perspective, 21st Century Cures codifies some of the policies that we had in the U.S., and is the slide I showed you before with the guidance that we put out, and it now codifies some of these policies.

When we look at what 21st Century Cures does, it really takes our guidance on mobile medical apps guidance, medical device data systems and looking at how we would approach electronic patient records as we described in the FDASIA Health IT report and codifies that. We will providing a lot more clarity on that aspect.

But as we do that, we have to look at what's happening in the current situation. It is really rapidly evolving in front of us and what we want to share with you today is we have taken all these aspects .

If you take a look at where we are in our situation, we have our current regulatory paradigm and we have unique aspects of digital health where we have been regulating products on a risk base for the longest time.

We have a certain capacity to review products. We also know that the current paradigm is best suited for products regulated today. When we match it with some of the unique aspects of digital health, especially in the software, you've seen the development timelines and the fast pace of innovation and iterations that have happened have changed and brought different challenges and considerations for us to think about. We also see emerging issues such as cybersecurity and interoperability push and pull the need for us to sort of be more transparent, at the same time be more secure.

We have also seen that the potential for increase in volume of applications have increased, and if you think about how software is being developed, how soon software can change over time, it really begs for us to think about how can we look at it differently and what paradigm should we think about that actually best suits for overseeing software in this space that rapidly evolves and changes at the same time. In the case of software, there is a need for changes to happen and how can the regulatory paradigm enable that.

When you bring it all together, when you take the work that you've done so far, the work that we have done in the international front, you consider the current 21st Century Cures and the modifications to the FD&C Act, and then take into unique aspects of digital health, it really takes us to the action plan, which really tells us how -- talks about three things. We will be defining our policies and providing guidance of how 21st Century Cures apply, how does the international framework sort of -- can be considered as part of our foundation -- and most importantly, we want to look at what does a new streamlined pathway really look like as we move forward.

The last part, I will speak on this a little bit, about building bench strength . As we have said many times, we want to be -- FDA needs to be at a place

where we can actually have a very strong conversation and a parallel conversation when we have submissions in house. At the same time, we want to be in line with the technologies that are evolving. So we want to build our bench strength with the right technical expertise.

And to that effect, as we launch into the pilot program, which I'm going to share the details shortly, we also will be announcing in the next few weeks, the launch of the entrepreneurs in residence program. We'll talk about that a little bit more further but let me go into the details of how are we providing policies and what we are providing guidance on next.

There are two big things we are doing. We are taking our existing policies, matching it up with the 21st Century Cures Act, and effect of the act on those guidance, and will be updating those guidance. But before we do that, we will publish an interpretation guidance that we plan on publishing by end of this year that will allow everybody to comment on how we are interpreting the 21st Century Cures, being transparent in that way, and then making changes to those finalized policies that we have.

That's happening this year. Early next year, in Q1 of 2018, we will be publishing two major guidance. One is on clinical decision support software that reflects the intent of the 21st Century Cures Act, as well as our review and our oversight on products that comingle, portions that are regulated and portions that are not regulated. We call that as multi-functionality but thinking about -- taking a look at how we would approach that and seek comment for that as well. So we will be publishing two draft guidance in 2018 and one major guidance in 2017.

We also are looking at the effect of 21st Century Cures and effect on the regulations that we have in place and we'll be updating those as well. So you

can see there is a lot of activity going to happen between now and Q1 of next year. We want to make sure that you all are aware of and that's covered in our action plan.

Let me share to the part where I think most of you guys are eager to listen to, where we need to go from here on. I think it's important to take into account what we have done so far, what we have in front of us, and take it to a place that really makes sense for FDA oversight to be in a place where it's in line with how software is being developed, it's in line with global regulations and regulators that are aligned to the foundational framework that we have been working on, and it's aligned to practices and real world experiences that folks use, and experience, and practice day-to-day.

So what does that look like? This brings us to this fundamental shift on how we would want to oversee technology and in the past, we have been overseeing technology as one product at a time. Somebody brings in information, we look at the product and the intended use, and we give them clearance or approval, or they can market a product. We are looking to shift to a fundamentally different approach where we would base the marketing authorization on a company's demonstrated culture of quality and organizational excellence.

So moving to a model where a company based streamlined regulatory approach for software as a medical device that relies on a demonstrated culture of quality and organizational excellence. So folks may be thinking, what does that mean? So let me just take you one step higher than that sentence and share with you how we are thinking about it. And just to share, this is a concept and a starting point to work through in the pilot, but this becomes a foundation for how we would approach in the pilot itself. A company that is pre-certified or goes through and proves or demonstrates a

culture of quality and organizational excellence would avail themselves to a pre-cert level. And we don't know the answers how many levels but that's something we will figure out.

Once a company is certified then based on the risk of the product that they're making or the products that they're making, they could be afforded a straight to market pathway or through a short streamlined pre-market review pathway. On the postmarket part because software is so connected and is so connected to the end users, we would ask those companies that go through this pathway to collect or understand how their users actually interact with their products and that's something that is available for software as a unique feature that's not available elsewhere all the time. So how do you sort of leverage the connectivity and how do you sort of leverage the computing power to understand how the product really works in the marketplace.

We hope that would allow people to start at a very low level who are not experienced or who are trying to enter into the marketplace and learn more about their product, and learn -- collect more evidence as the real world use evidence in practice -- and use that as a basis to substantiate higher level claims so to speak. So that's the paradigm we're looking at and that's what we call a real world data collection. We need to figure out together, as part of our pilot, how best we sort of do this.

So the concept is a starting point and you would take this to the next level as we start diving more into the pilot program itself and learning from everybody. Let me dive a little bit deeper into what we mean by culture of quality and organizational excellence. The goal for having an organizational excellence or a culture of quality and organization excellence is to have an ability to get a software as medical device to market faster. We also want the software to iterate based on real world experience.



We think that in the world of software, iteration is actually better for public health where things can be corrected and fixed based on how products are performing in the real world. We also want people who participate in this program to have an excellent regulatory experience and have great predictability. We are hoping that companies will strive for excellence from here on. We also are hoping to our objective of promoting high quality and effective innovation in this space, and we would want to create a very transparent pre-cert program that would actually help everybody understand where they stand and what they want to improve on, what they need to improve on.

So to start with, you can imagine the CQOE as balanced score card elements, as you can see here. We're starting with the five basic tenants, providing safe patient experience, delivering highest quality products, being clinically responsible, being cyber responsible, and being proactive versus reactive. These are the common things that FDA has always been wanting to sort of impress upon and (unintelligible) impress upon to our current regulations. So it should not be something new that we are expecting but it is rather a more holistic way of looking at it from the intent of the regulations than actually the regulations itself.

So how are we thinking about this? If folks can demonstrate through the different lenses that they have within their organizations and how they are actually managing their organizations through key performance indicators or other similar measures through their organizational perspective, through their customer perspective, are they learning and growing and do they have internal processes that can actually provide a holistic aggregate key performance indicators to suffice those key scorecard elements. That's what we are looking

for. Again, this is a very high level concept and this is something we will want to flush out further.

The fundamental idea here is to take one of those elements and look at it from multiple perspective, just like you would do in a business, just like your CEOs would do in a business where they would actually look for how the business is performing, not just by looking at one portion of their business but all options of their businesses and seeing what the outcomes of their processes that they have and the infrastructure they have put in place.

So that's the premise. So I'm sure you guys will have a lot of questions on this. I'm sure we'll learn a lot through this process itself, but it's really the concept that we want to start from and take it to the next level. I won't read all the bullets on this slide, but this is a snapshot of what we want to achieve or what we want to desire when we have a program like this. We want to enable very modern and efficient regulatory framework. It should be an easy to follow process. These are sort of the constrains we are putting on ourselves and we are putting on us as a sector and a community to make sure that the highest quality products are available.

We want to make sure that it's repeatable and it's scalable for organizations of any size. This program should be that it learns and adapts over time and to that effect, let me share this other picture with you where we think not only as you -- as makers of the software or makers of digital health tools would learn about how well your product is performing with real world use data, you want to understand also how effective is our program. So we're trying to create our own feedback mechanism to learn best and perhaps modify over time what's the right metric and what's the right KPI, what's the right scorecard elements, and what are the decision points that we need to adapt over time to create a system that will not only sustain for today but also sustain for tomorrow.

And that's really the vision we have here to make sure the regulatory paradigm also stays current on an ongoing basis as technology evolves. Last but not least, I'm going to talk about the component where we do want to take the knowledge and the learning that we have, that we put out through guidance documents, and create a toolkit, a development toolkit similar to a software development toolkit that's been available for software developers to create a regulatory development toolkit that would help not only the new entrants but also folks who are trying to create software solutions or digital health solutions in a space that may require many perspectives or that may require other considerations.

Now, we do have those considerations today in different formats, in different guidance, but may not be easily available or easily accessible, or not know where to look for. So we are hoping this regulatory development kit is a contextual based system that can allow people to ask the right questions, look for the right guidance that FDA has put out in the space of software and digital health, and guide them through the process so there is clear understanding how well they can make a product and be successful in the marketplace.

So to summarize, the concept itself has three big components, FDA pre-cert that allow -- that is company based, that will give us the trust in the company's making these products and having that trust would allow us to avail a faster, streamlined pathway to market, a regulatory development kit that will get the companies started off in the best standing to be successful, and lastly, for us at FDA, to learn and adapt a regulatory program that actually can stay current and where technology and aspects sort of evolve over time.

To actually take this concept to the next level, we announced a pilot program last week, and this pilot program is an interesting approach and a slight departure from what somebody would think about as a pilot program. Give me one second. We have some technical difficulties. You're probably not seeing my slides. Where I left off previously, I'm just going to back up one slide and we left off at the building blocks of the concept itself. But taking us to our pilot program, what we want to really do is sort of try to understand the details of the program and of the concept that we have laid out, and try to build it with folks who are going to be participating. But at the same time, you should be not looking at the pilot participation as the only folks who are going to be helping us build this. I want to encourage everybody to sort of provide their input and their knowledge as we move through.

So let me share how we are scoping the pilot, what we're going to do, and what we are expecting people to do from here onwards. The scope of the pilot we are choosing to limit it to software as a medical device itself, where we can say that manufacturing is developing or planning to develop software as a medical device, as defined by the international committee, MDRF, is the definition you're going to start looking at.

What does that mean? It means that software has its own medical purpose as defined in the FDNC Act is really what we are looking for. It can run -- it doesn't really matter where it's located and we've been discussing this concept for the longest time. What we don't want to include is things that are embedded in controlling medical devices like infusion pump or a cardiac pacemaker. Those kind of software is not what we're talking about. We are starting with really something really very small that is software as a medical device itself.

Now, there are some criteria and you can look at the guidance document that people -- that we have published, but really want to take a look at that scope and sort of taking it to -- and seeing we can select those pilot participants from that group of those developers. We are also looking at software function that is not excluded from medical device definition. So really, you want to make it relevant to the community we are looking at. So how are we going to run the pilot? As you can see, there are many unanswered questions and there are many things that we need to still figure out and we are looking at how we would go forward doing this.

The pre-cert pilot is really a mechanism for us to learn and we have a concept, which I shared with you. It's at a very high level and how do you take it to informing the regulatory program? We are going to take the first few candidates or the participants and input from others to try out, test it, and then further evaluate and refine as we iterate down this path towards the paradigm how you're going to take a trial run of a first few candidates, would apply to the next few candidates, and sort of iterate and use those learnings back towards building and answering some of those questions that may be open right now.

We are also looking at gathering input from others who actually may not be selected because I totally understand that having a participant pool of nine may not be fully reflective, but we are working towards an event in January of next year, early next year, to bring this conversation back in a public forum that we can discuss all the details and sort of learnings so far.

So what are the things we want to learn? Here are the things we know and we have questions for. How do we sort of do that? What are the pre-certification components? How do we leverage industry measures to benchmark these elements. If people are doing that, we want to learn from that. So we

anticipate in the early parts of the iteration we would probably benchmark that.

We will also develop and evaluate how to measure the criteria for those benchmarks, and from there on, we'll develop the certification correlated to that with the risk type of the software they are making. We also want to look at those boxes where we have questioned them, what decision criteria we could use, and we would develop that. And if there was a review and streamlined review needs to happen, what would that look like? What does the content look like, what does the method look like, should we still look at paper submissions or submissions of that kind, or should we look at some other artifact.

And then very last -- and more questions to follow is what does that mean to collect post-market data -- when and how -- what's expected. I think we need to work on all those things and if we want to work with all of you sort of work towards that and to answering those questions. And I can share with you that this is a lot of work and it cannot be done only by FDA, and I think we need to work together to sort of figure out how best we can sort of learn together and create a system that works for everybody.

Some of the things, before we launch into the pilot program, I wanted to just logistically want to say, we are opening applications now and will continue to sort of get applications until we suffice the criteria that we laid out in our federal register. And I won't read through all the selection qualities, but really what we shared in our federal register is about we would take applications or we would consider them, provide a statement of interest and expect to be part of this learning process along with FDA and with other stakeholders to sort of go-forward with it.

So here are some of the things that we are thinking about as characteristics of folks who would be part of the pilot program. We would want to have large and small organizations. So we understand how a large organization works and a small organization works. We want to get perspectives from our traditional medical device industry as well as perspectives from folks who are not traditionally in the medical device industry, but are thinking about entering this market.

We also want to learn from best in class and folks who are trying or looking at opening low to high risk software as a medical device. Here's some more details about what we expect the participants and CDRH to work collaboratively with. We'll work together. I think the point of this slide is to just share that we are going to work together on how we can determine the answers to this question and we will evolve as we iterate to the process itself. But really what we want to do is learn from what's happening best, translate to how can we actually meet our goals and the goals of the program and oversight, and how can we sort of figure out a way that would actually be helpful for everybody.

To summarize the pilot process itself, applications are starting now. We will select no more than nine participants and develop program elements developed by the participants. If folks are interested, they should email the statement of interest with subject line, "Pre-Cert Pilot Statement of Interest" to [fdaprecertpilot@fda.hhs.gov](mailto:fdaprecertpilot@fda.hhs.gov). I want to also emphasize one thing that even though the participants are only nine, we are also looking for input, which means that folks may have their own ideas and thoughts based on the concept and we can take those concepts and input it into our program itself, how do we sort of provide that -- provide a channel for that input is also important.

So to that effect, the federal register docket that we have created for the federal register notice that we published last week, would be a great avenue for folks to submit their input to the program itself and components of the program as we move forward. You should look forward for continuous communications on this and we'll be updating our website on how we are progressing, and we'll be as transparent as we can, making sure that the participants' confidential information is protected.

To end with, I just want to share the pilot is an important first step for us to explore the elements of the program. It is part of our continuous effort to be pragmatic and balance the benefits and risk of the digital health products, but most importantly, we want to collaborate and be a partner in this learning that we will have going forward to actually build a program that will be best suited for this fast and evolving technology space that actually holds the promise for bettering healthcare paradigm.

With that, I will just turn it back over to Irene but if you have questions, this is probably a time to ask questions. Irene, back to you.

Irene Aihie: Thank you, Bakul. Operator, we'll now take questions from participants.

Coordinator: Thank you. We will now begin the question and answer session. If you would like to ask a question, please press star followed by one. You will be prompted to record your name. To withdraw your question, you may press star followed by two. Again, press star followed by one to ask a question and one moment please for our first question.

Our first question comes from (Timothy). Your line is open. You may ask your question.



(Timothy): I just wanted to ask about how much of a burden could we expect in terms of site visits in the pilot and also, how often we would be providing any metrics or aggregated information just so that teams could try to understand what they'd be signing up for?

Bakul Patel: Thank you for that question. I think we are looking to be as open and sharing the information as possible, but we expect, for example, if you are one of the first few candidates or first few participants, we would probably have multiple site visits and not to revisit all things, but more about as we learn, we may have missed something in the first go round, but actually learn incrementally what we may have missed in the first thing.

So I expect a few for the first group, but it should be less of a burden for a site visit and it may not necessarily have to be a site visit, and things could be answered remotely as well. So that's one way of looking at it. And we would be open to working with participants to see what works best. The intention is not to disrupt the organizational operations, more about building a program that reflects what you guys are doing.

Coordinator: Our next question comes from Penny Levin. Your line is open. Go ahead with your question.

Penny Levin: That was my question. Thank you.

Coordinator: We'll go on with our next question. It comes from Diane Johnson. Your line is open. Go ahead with your question and please state your company name.

Diane Johnson: Diane Johnson from Johnson and Johnson. Bakul, I was hoping you could provide some insight on kind of the difference between what these site visits

would be like versus an inspection and is there any possibility that involvement in the pilot could lead to some sort of compliance action?

Bakul Patel: Thank you for the question, Diane, but let me just share with you, this pilot program is purely on products that are being planned on or being designed on or worked on right now, but more reflective over the company itself. I think if there are any issues, we will probably discuss with you ahead of time, but the whole idea is we want to pick companies who know that are really good at doing the software. So businesses who are excellent at making software and managing software, validating software, and designing them is really what we want to learn from.

So although there may be some issues that come out, but I think it may be beyond the pilot, but the pilot is more about learning rather than compliance.

Coordinator: Our next question comes from (Rahil Ata). You may ask your question and please state your company name.

(Rahil Ata): Hi, (Rahil) from (Vigo) Health. Thanks so much for the call, Bakul. Wanted to get some clarification on what information needs to be input on the statement of interest.

Bakul Patel: Yes, absolutely. So as we talked earlier, I think I can just share with you -- I'm back to the slide if you can see it. The statement of interest ideally would sort of show some history on how best used in managing, developing, and doing good software development as well as validating, as well as managing customers. So that would be one of the things. If you're using any kind of KPIs or other measures, would you be willing to share with us, or in the spirit of learning, and how do you think about from real world post-market data collection.

And those are the kind of things we would be sort of looking for. And really, we didn't provide a format and that was on purpose because we anticipated folks may actually have different ways of doing the same thing, but we wanted to really learn what's best. We would want to get an impression from your statement of interest that you are excellent and we -- and that's one of the key factors is the size of the company that you are, that you're representing. We're looking for both small and large but also we want to learn from the best so if you impress in your statement of interest how good you are and how some artifacts that help us get to that understanding or demonstrating that would be very helpful.

(Rahil Ata): And will there be any indication on -- or the risk of the device -- should that also be included?

Bakul Patel: Of course. Go back to our criteria. I think if you think this is a kind of risk profile you're working with or the software you're developing, we don't expect you to get it perfect but I think it will just give us an idea of the profile your company is sort of meeting. So it will be very helpful. This is a selection -- think about this as a criteria that we are using to sort of select participants and we want to make sure that we have diversity in the different accesses.

Coordinator: Thank you. Our next question comes from (Jaren). You may ask your question and please state your company name.

(Jaren): Hey, Bakul. It's (Jaren), Qualcomm. You mentioned really briefly the entrepreneurs in residence. Is that going to be a part of pre-cert or is that separate? Or are they going to be somehow aligned and what exactly will the entrepreneurs in residence be? Can you give a little more detail about it?  
Thanks.

Bakul Patel: Absolutely, thank you. The entrepreneurs in residence program is really using -- bringing in experts from the industry or people who are experienced in this industry to work side by side with FDA staff as we are learning through this. So sort of help us guide and build this program together. It's neither separate, neither part of this program, but it is one of the infrastructure that we think is necessary for us to be successful and having a program that sort of reflects and guides us through the process.

Coordinator: Thank you. Our next question comes from Tim Klein. Your line is open. You may ask your question. Please state your company name.

Tim Klein: Tim Klein, Johnson and Johnson. Does the agency ever think about in the long-term having this pre-cert program be something that would be a public database such that other companies would know, oh these ten companies, these 30 companies are now per-certified, akin to what the agency does with establishment registrations or other sort of more regulatory requirements. Are you able to speak about the agency's future vision here at all?

Bakul Patel: Yes, I think this is a good start. We will take all those best practices and being transparent as we move forward. But really what we want to make sure that we are transparent in the fact and it actually helps the goal of people striving for excellence, and how do we sort of go forward, keeping in mind protecting the company confidential information as well.

So yes, I think that's a great suggestion and I would encourage everybody to continue to suggest those things because as you know, we have to balance the company confidential information with the transparency that we want to make sure that exists. Now, we may or may not use existing tools but I think those mechanisms of being transparent will definitely be considered as we go along.

And that's something that we will learn what parts we need to be more open on and what parts we can't be more open on.

Coordinator: Thank you. Our next question comes from (Arja). You may ask your question and please state your company name.

(Arja): Hi, this is (Arja). I'm from (End Point). I had basically two short questions. One is are you also going to look at companies outside the U.S. for the program? And in addition, when you say prior experience in software development, is experience outside healthcare also accounted?

Bakul Patel: Yes, definitely outside healthcare, that's what I mean by we would look for people who are traditional medical device manufacturers or IBD manufacturers in addition to, we want to make sure that we also get people who are traditionally not necessarily in med tech but maybe outside of the med tech sector. In terms of the country location, we will look at applicants who are planning on this commercial distributing the products in the U.S. but again, I'll go back to my first principle is we want to learn and we want to make sure that we do have -- we do use the diversity of the participants as wisely as possible, balancing our resource needs and other things that is reflected in those nine participants.

But not to say that people outside of those nine participants can also learn on their own and perhaps even provide that input to us in other ways.

Coordinator: Thank you. Our next question comes from (Robert Eso). You may ask your question. Please state your company name.

(Robert Eso): My question has been answered. Thank you.

Coordinator: Thank you. Our next question then comes from (Ted). You may ask your question and please state your company name.

Ted Smith: Hi, Bakul. Ted Smith with (Rebone) Systems. Just a quick question on whether you'll be looking to any related industry standard certifications as part of this process? For example, (Rebone) Systems, we need to comply with high trust certification. Are any of these external certification standards that you think would be applicable or related to what you're trying to do?

Bakul Patel: We will be looking at -- standards are one way to deonstrate how do you measure and understand excellence. One of the fundamental shifts we are trying to make is we are trying to allow folks to demonstrate in their own way what their excellent standard measures are. So how do we -- I think that's the balance we need to learn through and make sure that we get there.

Now, for certain things like cybersecurity, certain best practices have become the norm and have been standardized and been used by everybody, and those are perfect ones to use standards. In other cases, some of those measures may differ from project to project, from product to product, or company to company, and we want to make sure those flexibilities are there, still focusing back on -- in the slide that I shared earlier in the concept -- about those key elements of safe patient experience, high quality, clinically responsible, et cetera.

Coordinator: Thank you. Our next question comes from Howard Luck. You may ask your question and please state your company name.

Howard Luck: Hi, this is Howard from Tide Pole. Thank you so much for this great webinar and this program. I'm really excited about it. I have three quick questions. The first is how are you thinking about site visits for teams that are largely

distributed and don't have facilities in the traditional sense. Is it important to meet the team or is it really more important to understand how the team builds its software?

My second question is about the time commitment for participants in the pilot program, especially for a small company. I'm curious how much time you would expect us to be a part of this. And then the third is, are there any thoughts on organizations -- encouraging organizations to publish how they do things, whether it's source code, or software quality system processes as a way of encouraging participants to share their best practices with the rest of the industry?

Bakul Patel: So great questions and suggestions and I'll try to remember your -- going from the top question. I think you're spot on and I think it reflects back to the very first question Tim had is what does a site visit mean and what does that look like. So I think it's important to sort of keep in mind that a site visit may not necessarily be a physical site visit. It could be remote. It doesn't have to be and I'd go back to the premise that we want to understand how folks measure, manage, and maintain for themselves those key scorecard elements that we pointed out earlier. That's one question.

I hope I'm remembering the second question. Can you remind me what was the second one? I forgot already.

Howard Luck: What do you expect the time commitment to be for participants in the pilot program?

Bakul Patel: I don't have a great answer for you in terms of exact number, Howard, but I think one of the key commitments we're looking for is would you be willing to work with us to sort of develop this. And for a small company, it may not

be a lot because there may be not much to think about. Or you may already have those things and then maybe in place. And in other cases, it might be much longer. So I really don't know and I think that's one of the discovery and unknowns that we'll have to sort of figure out as we move forward.

We don't expect this pilot to be multiyear projects. We want to make sure that we learn quickly. We report back in early 2018 and then iterate from there. So that's how we are thinking about it.

Howard Luck: Do you expect companies to publish their software or their processes as part of participating?

Bakul Patel: Yes, the level of transparency will differ for every company and how we sort of move forward in the type of transparency will also differentiate. I think somebody previously asked would we be sharing the CQOE score if that's the way we end up going to give people an understanding of what that means, or it's a mark, or whatever that level we end up doing. We would want to make it as transparent as possible.

Now, whether we -- FDA does it or somebody else does it, still to be determined. But I think this is where we are heading and I think the need you're pointing out is if there is a way to sort of do this better and in a more efficient way, we'll be looking for those methods.

Coordinator: Your next question comes from (unintelligible). You may ask your question and please state your company name.

Jeff Carlyle: Hi, it's Jeff Carlyle from (Numo) Systems. Thank you for this webinar. I think the thinking you put into it is really outstanding. So thank you. You mentioned specifically that this is aimed at software as a medical device and



not at embedded controller stuff, yet it's patient centric. So in almost every application that's patient centric, I see a combination of embedded control and workstations, and networks, and cloud computing.

So could you give some examples as to what projects would be eligible and perhaps which projects would not?

Bakul Patel: Absolutely. I can give you a couple examples. I gave a couple examples of some projects that would not be, like an infusion pump embedded software, or pacemaker embedded software, or some other products that we traditionally regulate as embedded controller software would not be included. But anything that does take patient information and does advanced analytics and provide a diagnosis or a cure, or a recommendation per the definition of software as a medical device and the guidance that we put out, and meets that definition of a medical device is something that we would want to consider.

So something that takes an EKG waveform and now detects a cardiac condition that definitely diagnoses it, or it takes something else and diagnoses a disease or a condition would be something that we would be interested in looking at.

Now, one thing to keep in mind is there may be products that use a competing platform's peripherals and collect that data, and then does analysis. We would consider those products that just uses generic peripherals or generic sensors, input devices or output devices, to make a medical purpose intention, we would be considering them as part of the pilot as well.

Jeff Carlyle: Well, the confusing part is that an IV pump in the future will be exactly the opposite of what you said. It will be an embedded controller. It will be a workstation. It will be a network. It will be a cloud computing amalgam

because the pump isn't -- you already mentioned patient centricity and if the patient is at the center, then the pump does not become the center of the universe. It's no longer standing alone. It's part of a patient centric system. So it gets a little confusing as to what...

Bakul Patel: So just to give you perspective and not to disagree with you, but in fact, I totally agree with you where you're going with this. But in order for us to learn from the participants and we have to crawl before we walk, and this is exactly what we're doing is we're starting with a very small scope, with a very small, narrow sort of perspective and hopefully those things will be transferrable to other areas as it evolves. So that's really what we are looking at and it's not because this program will be exclusive but it's more about can we start here and can we learn in this -- the fastest moving area that we know of today and apply it eventually down the road for other software.

Coordinator: Thank you. Your next question comes from (Natan). You may ask your question and please state your company name.

(Natan): Hi, (Natan) coming from (Sports D). My first question is you mentioned that we look to correct real world, post market performance data and I just want to know if you could explain a little bit more about what kind of data you look to collect. And second short question is you mentioned you're looking for companies with existing track records and I was wondering whether that means that you do already have to have some sort of (unintelligible) clearance in place, or whether you're also looking for companies that are free (unintelligible) (510-K).

Bakul Patel: I'll take the first one is about the real world data collection and performance data collection. That's a concept that we've been talking about a lot where we said in the world of software, you are exposed to the user in a very intimate

way, that you can learn every interaction, how well the software works, and how well the software's output is used by the user. So we are encouraging people to collect that information, while the software is in use and that's what we mean by that.

And you can imagine all kinds of user behavior, including clinical data or clinical evidence that can be generated or created based on that interaction. So that's what we are envisioning. And the second question -- can you repeat your second question?

(Natan): Yes, sure. Second question is about you mentioned you're looking for companies with existing track records. Does that mean you're looking for companies that have pushed a bunch of products out into the market already or are you open working with companies that are, let's say, younger in terms of the product life cycle?

Bakul Patel: We are open to companies at all stages but really, going back to is if we can learn -- and this is why we are talking about people may not be necessarily in med tech, but they maybe in an adjacent sort of market that have a good track record in other products, that may not necessarily be medical devices. But that learning would be very beneficial for us to sort of take it.

So we are not limiting people that have previous experience or not. It's more about making sure that we are looking at people who know exactly how to develop software, how to maintain it, and actually manage to those five elements that I mentioned before.

Coordinator: Thank you. Our next question comes from Larry Ruben. Your line is open. Please state your company name.

Larry Ruben: Hello, my name is Larry Ruben. My company is called (B-Care Link) and my question, and it is connected to the last question that was just asked, and it is, if my company is in the middle of doing clinical trials, is that something that can also be used as part of the existing track record, or as a key performance indicator?

Bakul Patel: So I'm not fully understanding your question but I'll try to answer it. You asked the question whether your company is currently in a clinical trial.

Larry Ruben: Of its software product, yes.

Bakul Patel: If you're looking at a product -- so this may meet the criteria whether you're planning to develop or developing. So I think you may meet the criteria of that first prong of what kind of companies we're looking at.

Larry Ruben: That answers my question. Thank you.

Coordinator: Thank you. Our next question comes from Jeffrey Kendall. You may ask your question and please state your company name.

Jeffrey Kendall: Jeffrey Kendall with Koni here. The question is would the FDA consider pilot participants that are collaborating together, such as a software development company and a traditional med tech product company as a joint participant in the pilot program? Or would those need to be individual representatives?

Bakul Patel: The way I think about this, it's interesting you guys are asking all these tough questions, but the way I think about this is we are looking for a developer of software. So if it's made of two or more entities then fine. It could be part of a larger organization. That's fine too. But if you've got to sort of trust in a business unit or a group that's developing software so we can trust that the

product that they're making is of high quality so they can avail straight to market or through a streamlined process then really what we are looking at are that aspect level.

So the results of having two or more parties be part of a development organization may or may not include complexities but that may be a good learning to have as well.

Coordinator: Thank you. Our next question comes from Kelly Collins. You may ask your question and please state your company name.

Kelly Collins: Hi, I'm Kelly Collins from In Touch Health, and I want to try to get some clarification in terms of how one determines if we qualify to be a possible volunteer for the program, in that going back to the Cures Act with the amended definition of software as a medical device, if those types of companies or products are no longer regulated by the FDA, will they fall under oversight of the digital health unit?

Bakul Patel: So this pilot program is all about what falls within the definition of a medical device and we would continue to sort of focus on that. Things outside of our regulatory jurisdiction is really not in the purview of FDA and we would not be looking for that space.

Coordinator: Thank you. Our next question comes from (Allison). Your line is open and please state your company name.

(Allison Komiyama): Hi, this is (Allison Komiyama) from Acknowledge Regulatory (unintelligible) really interested in the regulatory pathway of software and medical devices, but they -- essentially, they -- some of them are marketing as

general wellness currently and their goal is to change their indications so that they will be regulated by FDA.

We currently have some pre-submissions that we like to send but since the news last week of this pre-serve pilot program, we'd love to see if we are the right fit for this. Can we send in the pre-submission as our pre-cert pilot certification request? Or if not and if we don't get selected for it, can we still submit that pre-sub to you guys, to your team?

Bakul Patel: So thank you for that question. That was one of the questions I had received earlier. I think folks, I would encourage everybody to apply and I think it will make our jobs difficult in selecting those nine candidates but I would not shy away from applying. So that's one. Number two, if your companies are already on a pathway to get a (510-K) and want to be in market, you should also look at this pilot as a learning opportunity for us. So it is going to be an iterative process where we are going to learn. So as a result of that, I think you will be exposed to some of the uncertainties and if you're looking to be certain, to be in the market now, I would encourage you to sort of engage FDA in the traditional way.

But this is truly about a collaboration that we are looking for, for people who can help build it, and be invested for the longer run.

(Allison Komiama): Would the traditional way be a de novo?

Bakul Patel: I think you would have to contact either -- you can contact (unintelligible) software product and additional health product. I would recommend you write to Digital Health, email box ([digitalhealth@fda.hhs.gov](mailto:digitalhealth@fda.hhs.gov)) and we can get you the right pathway if you're regulated or not, and we can get you in touch with the division to sort of have those discussions.

Coordinator: Thank you. Our next question comes from Martin McCarthy. You may ask your question and please state your company name.

Martin McCarthy: Hi, I'm with what was formerly known as Medical Device Daily and is now known as BioWorld Med Tech. Thanks for taking my question. The previous questioner raised an issue that I'd like to get a little bit more information on. One assumes that this pilot program will be principally or entirely for Class 2 devices as Class 1 devices are unregulated and I don't imagine that a pilot program is really appropriate for a PMA type application, not that I am aware of. Any strictly software devices that have gone through the PMA channel anyway.

But when I look through the Federal Register and I see successful de novo applications, and when I see something in the way of a product code, I never see product codes or de novos for software. And so I'm wondering if you could give everybody a brief summary of the circumstances in which a de novo application might be appropriate for a Class 2 device. And I don't know if you know how many pro codes there are for strictly software devices, but I haven't seen any and I'm curious as to whether all software as a medical device items are lumped together under the code of federal regulations. I just haven't seen any indication there's a diversity of pro codes or entries into 21 CFR.

Bakul Patel: So I think you're way ahead of us in terms of product codes and regulations. Even classifications for that matter, what we are starting off with is taking the framework that we put together and work together with the international partners, and using this pilot program to really taking a big step back and then determining what that pathways would look like. And that will result into a different, maybe perhaps the same way of pro codes or maybe a different way

of categorizing these products with risk levels and the assurance levels we need to sort of put them into those buckets.

So to be defined is the short answer but I think that's one of the outcomes we want to learn as well from this pilot is what is the right mechanism for us to categorize this in the U.S. law.

Coordinator: The next question comes from Bill Evans. You may ask your question. Please state your company name.

Bill Evans: Hi, this is Bill Evans from Rock Health. Just curious to know, we work with a number of companies in the space that are contemplating or already fall under they believe the software life cycle to find an IEC 62304 (unintelligible) for quality management systems, ISOs as well. To what extent will this pilot program explore explicitly adapting or extending these standards? Alternatively, I guess, is it the vision here that this pilot only involves companies that are believe to fall outside of those standards under current FDA regs?

Bakul Patel: I think we're looking for both and we're looking at how best we can -- rather than people conforming to a standard, we are looking at what people normally do, to do best software, and then what are those practices. In fact we are -- you can imagine this as learning from what people do best to create a standard or create a paradigm that actually recognizes what is best. So I know there are standards that have been created to what we have -- what we know so far is best and can we validate that? Can we allow people to demonstrate that in a way that we all can get on the same page from the same intent and goals perspective for the elements I described.



So I don't know if I answered your question but yes, the answer is if the standards are available, we'll take them but if people are following standards, but are not able to demonstrate in a very cohesive way, we would want to understand that. I guess the bottom line is you want to understand the natural state of how best offer is developed.

Coordinator: Thank you. Our next question comes from (Barca). You may ask your question and please state your company name.

(Barca): Hi, my name is (Barca) from (Sentionix). I'm wondering about -- hello?

Bakul Patel: Yes, we can hear you.

(Barca): Oh, sorry, okay. I'm wondering what about companies that don't have a product yet but are in the development stage. Is that something because they won't be able to collect metrics, right, I mean if their product is not yet approved. So is that something that would still be qualified under this program?

Bakul Patel: So we are looking for an entire life cycle management experience what people do. So it may not necessarily be you have -- the company may not necessarily have experience putting a medical device out to the marketplace, but if they have experience doing the same thing in other sectors but now, they're trying to apply those best practices in this sector, we would want to learn from that as well.

So that's really what it is.

(Barca): So a follow-up on that, if the company is commercial in a Europe market or something, that would be acceptable in terms of collecting data or understanding that?

Bakul Patel: Yes, we would not shy away from people who have done good practices in other areas.

Coordinator: Thank you. And our next question comes from Jonathan. You may ask your question and please state your company name.

Jonathan Helfgott: Hi, Jonathan Helfgott from Stage 2 Innovations. Thanks again for leading such a wonderful collaborative opportunity. My question is does acceptance and participation in the pilot program automatically enroll a company into the actual software pre-certification program, thus allowing the company to receive the potential benefits of the program, such as decreased submission content and/or faster review of marketing submissions?

Bakul Patel: Like I've been repeating, Jonathan, I think this is going to be a learning process for us rather than sort of definitively saying, once you are in the program, you automatically get an approval or a clearance. That's really not where we're heading but I think if we partner -- we have the right diversity in the nine participants, we would love to sort of work together to a place where we would want to understand what a streamlined submission would look like, what it would mean pre-market, post-market data collection would look like.

And as a result of that, yes, there may be a pathway that we could say it does need clearance to go to market or not. So I think that's to be determined but what I want to leave with is really trying to make this as a learning and iterative process that we can all work together towards.

Jonathan Helfgott: Got it, thanks Bakul.

Coordinator: Thank you. At this time, I'll turn the 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 webpage at [www.fda.gov/training/cdrhlearn](http://www.fda.gov/training/cdrhlearn) by Wednesday, August 9. If you have additional questions about today's presentation, please use the contact information provided at the end of the slide presentation.

As always, we appreciate your feedback. Following the conclusion of the webinar, please complete a short 13 question survey about your FDA CDRH webinar experience. The survey can be found at [www.fda.gov/cdrhwebinar](http://www.fda.gov/cdrhwebinar) immediately following the conclusion of the live webinar. Again, thank you for participating. This concludes today's webinar.

Coordinator: And this does conclude today's conference. We thank you for your participation. At this time, you may disconnect your lines.

END