U.S. FOOD AND DRUG ADMINISTRATION

FOSTERING DIGITAL HEALTH INNOVATION: DEVELOPING THE SOFTWARE PRECERTIFICATION PROGRAM

PUBLIC WORKSHOP

Day 1

Tuesday, January 30, 2018

8:43 a.m.

National Institutes of Health (NIH) Campus

9000 Rockville Pike

Ruth L. Kirschstein Auditorium

Natcher Conference Center, Bldg. 45

Bethesda, MD 20892

Reported by: Casey Smith

A P P E A R A N C E S

FDA LEADERSHIP:
JEFFREY SHUREN, Center Director
Center for Devices and Radiological Health
BAKUL PATEL, Associate Center Director
Center for Devices and Radiological Health

PANEL ONE:
DANELLE MILLER, Vice President of Global Regulatory Policy & Intelligence
Roche Diagnostics
HOWARD LOOK, CEO & Founder
Tidepool
YONG JIN LEE, Senior Vice President
Samsung Electronics
DIANE JOHNSON, Digital Health Policy Lead
Johnson & Johnson
LARRY CARRIER, Head of Global Regulatory Affairs
Verily Life Sciences
ALEX BISIGNANO, CEO
Phosphorus

A P P E A R A N C E S (Continued)

ADAM PELLEGRINI, General Manager
Fitbit Health Solutions
DAVID ARMOR, VP of Quality & Regulatory Affairs
Pear Therapeutics
JENN NEWBERGER, Senior Legal Counsel
Apple

PANEL TWO:
LINDA RICCI, Health Scientitst
Office of Device Evaluation
JOHN MURRAY, Expert Regulatory Review Scientist
Office of the Center Director
MARTIN HO, Associate Director for Quantitative Innovation
Office of the Surveillance & Biometrics
MARISA CRUZ, Senior Medical Officer
Office of the Center Director
ADAM BERGER, Ph.D., Personalized Medicine Staff
Office of In Vitro Diagnostics and Radiological Health

A P P E A R A N C E S (Continued)

CATHY BAHR, Digital Health Expert Advisor
Office of the Center Director
ESTHER BLEICHER, Senior Policy Advisor
Office of the Center Director
FRANCISCO (CISCO) VICENTY, Program Manager
Office of the Surveillance & Biometrics

PANEL THREE:
CARA TENENBAUM, Senior Advisor
Office of the Center Director
KATHLEEN BLAKE, MD, MPH, Vice President of Healthcare Quality
American Medical Association
ADAM BROWN
Head of Diabetes Technology & Digital Health,
Close Concerns
Senior Editor, diatribe.org
DR. ANDREW AUERBACH, Professor of Medicine
UCSF Center for Digital Innovation

A P P E A R A N C E S (Continued)

DR. NAOMI ARONSON, Executive Director
Blue Cross Blue Shield Association

PANEL FOUR:
ZACH ROTHSTEIN, Associate Vice President for Technology & Regulatory Affairs
Advanced Medical Technology Association (AdvaMed)
DR. ASIF DHAR, Principal Chief Health Informatics Officer and Therapeutic Area Transformation Solutions Leader
Deloitte
ANAND IYER, Chief Strategy Officer
WellDoc, Inc.
ANNA LIBMAN, Director of Regulatory Affairs and Business Development
Experien Group
MICHAEL KIRWAN, Vice President
Continua

A P P E A R A N C E S (Continued)

PANEL FIVE:

TIM ANDERSON, President
Anderson Leadership

KIRK HOLMES, President
Holmes & Associates

HOWARD ROHM, Co-Founder & President
Balanced Scorecard Institute

GEORGE ZACK, Co-Founder & Principal
Two Harbors Consulting

P R O C E E D I N G S

MR. PATEL: Good morning. Can I hear a good morning? Thank you. It's an exciting day. I'm actually very happy that you're taking your time out of a day to come here to spend a couple days with us on this exciting program. Welcome everybody. If you guys can take seats, that'll be great. Here's what's going to happen in the morning, just in the next few minutes. After I speak, Marisa is going to introduce the logistics and talk about what's going to happen for the rest of the day and next day. And I'm going to have Jeff Shuren, Director of the Center for Devices and Radiological Health give an opening remark. He is probably the most modest visionary that I have known in my life and he's going to share with us what is it that the Center is doing and how it relates to the program. So with that I'm going to turn it over to Marisa.

MS. CRUZ: Thank you, Bakul and welcome everyone. I definitely echo his welcome. We're excited to have you here. We're looking forward to some productive and inspiring conversations over the next few days.

As a few housekeeping items, sorry, again, I'm Marisa Cruz, I'm a Medical Advisor for the Digital Health Unit at CDRH. So housekeeping items, we've attempted to save at least a few trees by using the QR codes that you'll see on posters in the lobby to direct you to FAQs about the precert program, to a copy of the addenda and to biographies of the panelists you'll hear from today.

As you saw from the signs on the door, food and drink is not permitted in this auditorium. But we have scheduled some breaks throughout the day and coffee and snacks are available at the cafeteria upstairs. Free wifi is also available at NIH Guest and no password is required.

As you heard from Bakul, we're going to start off this morning with opening remarks from Dr. Jeff Shuren, CDRH Director for FDA and from Bakul Patel, Associate Director for Digital Health. Before lunch we're going to hear from the pilot participants and then from FDA staff about their respective experiences developing a preliminary framework for our precertification program.

An open question and answer session will follow each panel and we'll cap off the morning with public comments from preregistered speakers. For these question and answers sessions you're welcome to walk up and ask your questions at the mic stationed in each of the center aisles. You also have the option of submitting a written question to our runners using the note cards that were provided at the registration desk.

Our virtual participants are also welcome to submit questions during these sessions using the FDA precert email address, which you can find on our website and in your confirmation email. And lastly, all media inquiries should be directed to Stephanie Caccomo, who is standing at the back of the auditorium just over here. I think that is it. With that I'll turn it back to Bakul. Thank you very much.

MR. SHUREN: Good morning everyone. Welcome to our two-day public meeting on developing a precertification program. The North Star for the FDA's Center for Devices and Radiological Health which guides everything we do and we put in place in 2012, is our vision that patients in the US have access to high

quality safe and effective medical devices of public health importance first in the world. And as you've heard from us many times is it's not about a competition between countries, simply a recognition that we want technologies to benefit patients. But technologies are limited value to patients if they don't have timely access. And first in the world, there's simply a good metric of timely access.

And we face a number of challenges in achieving that vision. And we think that vision is so important because if we want to accomplish our mission of improving the health and the quality of life of patients it's not just making sure technologies are safe and effective, they're beneficial. We want to drive the development of safer more effective technologies, drive innovation and assure that patients and practitioners have timely access. Otherwise we don't really get the power of the devices that are made.

We face a number of challenges here in the US. One of them is that we have a great regulatory standard for assuring patient's safety and to come to market.

It’s reasonable assurance of safety and effectiveness. But because it’s one of the highest standards in the world it often entails the generation of much more evidence, particularly if a high risk and innovative lower risk technologies to come to the US market and meet that standard than it does for other countries. And that can create disincentives for innovators to bring their technologies to the US early, if at all.

So since 2012 our strategic priories have been focused around how can we sufficiently reduce the time and cost of the total product enterprise and life cycle such that innovators view the US marketplace more favorably, but not sacrifice that standard of reasonable assurance of safety and effectiveness. That’s what we’ve been driving at.

And we’ve made a number of significant changes and improvements. And as a result, when I first came to the Center in the fall of 2009 the end of that calendar year we had approved 24 novel technologies. Almost every year since then that number has gone up. In 2017, it was 95, a four-fold increase. It is the highest in the modern day medical device program. The

only year that was higher than that was 2016. Only year higher than that was 2015.

Some of the changes included putting in place patient centered flexible benefit risk paradigms. And it allowed greater flexibility around the inflection point for when technologies are introduced into the US marketplace. One of the hallmarks as a consideration of where you strike the right balance between the data necessary in the premarket to have a product go on the market versus what can we rely on in the post-market setting. But we face a number of challenges in this sort shift to post-market. Because when we get clinical data and we rely on traditional clinical trials we have challenges getting people to enroll because patients lack an incentive to enroll in those studies once the technology is otherwise available.

So we have been looking at how can we better leverage evidence that’s generated in routine care, what we call real world data, but solve the challenges in using that information? How do we drive down the time and cost and increase the value and use and systematic use of real world data to support

technologies both coming to market and generating evidence in the post-market setting? The value too is we have better data on the real use of technologies and their true benefit risk profile. And that has led to our efforts to establish the National Evaluation System for Health Technology, or NEST. And that approach will be critical in some of the things we are thinking about in a new paradigm on digital health technologies.

Now, digital health technologies hold tremendous promise. We've already seen some of that value. So we may be looking at entirely new kinds of technologies and functionalities, particularly taking advantage of more intelligent systems and learning systems, or enhancing existing functionalities, like the more precise implantation of ocular implant devices. Connectivity between technologies, generating so much more power and functionality than we could have before and then the ability to monitor patients remotely and provide care remotely through telemedicine.

But also digital technologies raise some unique challenges for us as well in achieving that

vision. The medical device regulatory framework was created forty years ago. And since then there have been incremental changes and improvements, but not fundamental changes. And they were really based around a risk based approached focused on products. And those products are hardware. And it got adapted over time for hardware with maybe software as a component. But it was never designed where the technology itself is software, software as a medical device. We really need rethink the paradigm entirely because there are huge differences, as you know, with a hardware based technology and truly a software technology.

In hardware you can kick the tires and get a sense of what it does. And the knowledge you generate from a product in that category is often transferrable to other products in that category. You can observe a lot of the effects on patients. And the innovation cycles tend to be on the order of months, sometimes years. Often the functionality doesn’t change, there were incremental improvements. But when we deal with software as a medical device you can’t simply look at it to understand what it does. The impact on patients

can also be far more indirect and different. The innovation cycles on the order or weeks, not simply months or years. And the changes in that technology can be profound, not incremental. And what we understand from looking at one software that's not so easily transferable to another. And so that traditional paradigm of product by product looking at every moderate risk and high risk technology just does not work well. And so we have to change that.

And so as we think about that new paradigm it sort of raises the question: what should it look like? So I mention over the past few years our strategic priorities and then focus around time and cost of the total product life cycle. In 2018 and for 2020 we have recently put out new priorities that build on our prior work. And we've said the following, we think the actions we're taking are the right things, stay the course. But we need to apply three approaches more systematically. That's what we're focused on.

One is our employee engagement opportunity and success. A second is simplicity. And the third is collaborative communities. And I want to take a moment

to talk about simplicity and collaborative communities because it's what we're dealing with today. The idea of simplicity is that we are continually streamlining our policies, our processes, our programs and approaches. It means we stop doing what is not sufficiently value added. It means that we make our policies as straight forward as possible so that two people who apply them come out at the same place with the same results. It does not mean we are changing our regulatory standards. It does not mean we don't continue to rely on robust, valid scientific evidence. And quite to the contrary it means a better use of our resources. And it is consistent with, encompasses and goes beyond the least burdensome provisions that were the importance of which were recently reemphasized in the 21st Century Cures Act.

We have already started to go down this path. In 2011 we issued draft guidance on mobile medical apps in response to queries from mobile act developers who were coming into the healthcare space asking for clarity around our regulatory expectations. And we said at the time we focus on the functionality. We're

agnostic about the platform. We'll treat functionalities the same regardless of platform and so on. But we also took the opportunity to say, you know what, there are so many functionalities out there that are low risk. We're seeing innovation occur and we could spur more innovation if we took a light touch. So we engaged in a massive deregulatory effort back then and said for all these functionalities we're going to stop looking at that. If you will, let a hundred or a thousand flowers bloom. That was an example of simplicity in the early stages back then. And then we started to apply it to medical device data systems. General wellness claims. And we have been building on that ever since.

We then said we need to rethink the paradigm, but when we do it let's do it across countries. So we've been leading a working group in the international medical device regulator's forum for a few approaches on software with a medical device, but have it harmonized across other countries. And just a few weeks ago we put out the fourth document in a suite. And that now kind of brings things down to maybe the

50,000-foot level. But we have to go deeper still. And that's what we're talking about.

So when we think about simplicity, and as I said, encompasses the least burdensome but goes beyond, one of the principles in least burdensome we articulated in a draft guidance in December of 2017 was the idea of flexible regulatory paradigms. The idea is rather than take technologies and put them down in cookie cutter pathways, design the regulatory paradigm around the technology. What are its unique evidence generation needs, patient access needs, innovation cycles?

And one of those approaches is this idea of precertification. Go beyond the traditional regulatory model of risk based product focus to a firm based approached where appropriate. So essentially can we trust but verify that that firm does a good job within this technology space and as a result maybe not have to look at all those products or modifications before they go to market and before those changes are made. That's what precertification is about.

We first floated this a good two years ago and

are trying to build momentum behind this ever since. In fact, we've already applied it to some technologies. In 2017 we put out an approach for direct to consumer genetic health risk tests. That was precertification. We essentially said you have these tests, like next generation sequencing, you look at a myriad of genetic variance for which there may be associations with increased or decreased risk for particular diseases. We said rather than coming in for every single claim, if the developer comes to us once with one claim and can show they meet expectations for demonstrating their accuracy and identifying the relevant genetic variance, that they are meeting expectations in assessing the clinical evidence to support the claim and they can conduct good user comprehension studies, thereafter they don't come back to us. That is a trust but verify, that is a firm based approach. That is a kind of precertification. That's the idea that we're talking about.

The second strategic priority is collaborative communities. A recognition that we are most effective when we work with other stakeholders in the community

to solve problems. And a collaborative community is an ongoing forum where the key stakeholder groups in the community come together through collective responsibility to solve shared problems, problems unique to particular members and achieve desired outcomes.

What's unique is that when government is at the table, when we're at the table this is not the typical command and control. It's not collaboration on our terms. It's not the we're in charge, we'll give you -- we'll let you come in the door and tell us what you think. It is we have an equal seat at the table. We're one voice amongst many. It means that we try to solve as the community, not as the government. It means give and take. It does not mean we sacrifice our standards because we have to be those guardians of the public health. But how we do it and what we're willing to do has to shift.

We already are starting that approach in a number of settings. Our creation of NEST I mentioned has a governing committee of representation from all the key stakeholder communities. We have a seat the

table. We have an equal voice, but we don't run the show. We have proposed a similar approach in next generation sequencing for establishing standards for analytical validity and for evaluation of the evidence to support new claims. And we've proposed the same in digital health. We think in moving forward, not only developing precertification program, but all our work in the digital health space we should be establishing one or more of these collaborative communities where government has a seat at the table, but it's not our command and control.

In the movie Field of Dreams with Kevin Costner, Kevin Costner was asked "If you build it, he will come." The more modern version I think is "What should we build that you will come?" That's what we're talking about over the next two days. But whatever we build we will do this together.

So thank you very much for coming. I look forward to the dialog over the next two days. Please do not be shy in breakout sessions. There is no such thing as a bad idea. Not until afterwards at least. And let me turn it over to Bakul Patel, our Associate

Director for Digital Health.

(Applause.

MR. PATEL: Thank you. And so folks have heard me talk before about collaborative communities and building this together is exactly where this starts from. We have been building this together, we couldn't do this ourselves. And this is exactly what these two days is about is building it together. So people who are in the room I have actually had many people come to me and say, oh, how can we be a part of this? You're already part of his by being here. So be here, help us build this together.

I'm going to take a few minutes to walk us through how we started, where we are and where we are going. And I will end my talk with talking about, you know, what are we going to do for the next couple days, for today and tomorrow. So give me a minute to sort of turn over the slides.

It is important to keep in mind we are talking about simplicity and that's really where we started. We started also talking about there are some interesting challenges and opportunities that exist for

software. So we had to come up with a place where we needed to start. So I had a couple people to talk to me this morning and saying “Why doesn’t it apply to everything we do?” It can apply to everything, but we needed to start to a place where we can actually have this problem understood, figure out a way going forward, create a framework that can sort of, that can actually help us build it right. It’s about building it right and not about making sure that it’s highly regulated or anything like that. It’s about having the same standards, it’s about having -- making sure that the program and the pathway that we create is actually so good that people want to be part of this program, part of this regulatory approach. And that’s the goal of this program.

So let me walk you through how we thought about this. A few years back, as Jeff mentioned, we started thinking about how do we think about this space in a way that is actually in line with how businesses are run in the space. And you look at where the trend setting trajectories are going and you can see that there are challenges in our current paradigm and there

are evolutions happening with the space. Digital health holds a promise that we all are obligated as a community to deliver it to the patients and the individuals that we serve.

So looking at the timelines, there are different things that are happening in the space in software. When you think about the concept of zero coding, the concept of, you know, automation and creating code and testing and validation that's a different concept than what we are used to sort of seeing. When you think about the timelines, when you think about, you know, twelve or eighteen months timelines for delivering product and now you have continuous delivery of operations, that's a different kind of mindset that brings -- the software brings to the table.

If you think about the opportunities and challenges that come with it you have issues like cyber security, interoperability. There's a demand that sort of goes with the connectivity and the (inaudible) of software that's in your pockets today. How do you sort of bring that together? And when you pull it all

together you also have a very, I mean, from a very internal FDA perspective I can say today we get about 3500 plus submissions for 510Ks. That is a potential for that to be completely big and exponential if you didn't think about a pathway that was actually really streamlined and making sure that products are heading into the market in the same way. That we expect them to be highly safe and effective.

So how do you get there? So we proposed -- this is actually, I took one of my very early slides and said there's an opportunity here. How do we sort of take this opportunity and turn it into like this fundamental concepts of can you please certify somebody to have that trust that these people can actually build products that we get on the same page what those criterias are? We didn't have an idea of like what that meant and what that looked like, however, we had put it in a flow. And then we had this concept of how do you take this concept, this tool that exists in software development, the software development kit and how do we apply that to the regulatory systems? And so can we create a regulatory development kit.

And then last but not least is the third component in my mind is whatever system we create has to be a learning system. We can't do this as an open loop where actually we have something in place and we have revisited it over time. I think we need to build a system that learns over time, that's informed with information. We're in the day of information age and we need to sort of leverage that.

How do we do this? So we last year, last July we announced this program where we ask people to partner with us and give us ideas and sort of input to how we should build a program that's company based. And I will talk a little bit how we are changing, evolving to a company-base approach where we trust these companies to build software as a medical device that's based on some criteria. And we called it Culture of Quality and Organizational of Excellence.

I'll go into detail about what that means. But let's just talk about what does this program look like? And but where does it -- what's the scope of this program. So we started small. Some would argue it's not really that small. But we started small by

saying let's just focus the program to something that's just software. We can put our bounds on it so we don't have something in the hardware interactions and other things that are sort of, you know, making the problem difficult. So we said if it's just software it takes input and processes in and provides output that's necessary for a medical condition or a medical purpose. Can we use that boundary and apply that construct to a program that can at least get off the ground?

So we said if we were to certify a company and build trust, take the software as a medical device international work and the spectrum of that and what kind of products can go straight to market? What kind of products could look at different view? We're actually looking at that threshold as number one. We're also looking at what should this review look like? And I said it to many of you, you probably heard me talk about this, we're not talking about submissions right now. We are talking about review. So the assurance that FDA can provide in terms of assuring safety and effectiveness and high quality, what should that look like. So we are revisiting fundamentally

what the review should look like as well.

And if you take the next step, in order for -- we said this is a voluntary program. In order for us to sort of have trust and have some feedback that these products to the market with a different system and know they're performing well, we wanted to make sure that there is enough instrumentation in the software, one. There's enough information that's coming back to the community from a real world perspective to know how these products sort of behave and are performing in the marketplace.

Taking the concept one step further, Jeff talked about NEST. And that's exactly what we are talking about here is how do you sort of build the product in performance issues, the clinical performance and then bring it back to a larger sort of ecosystem that can take that information and then and from the program itself? This is what I mean by the learning. The system needs to be learning. And this is exactly what we meant by that.

Let's walk through to see what this program Can achieve. We want this program to be scalable. We want

this want this program to be easy. We want this program to align as closely as possible to how businesses run and make products. That's extremely important. I'll also throw out one couple other things to talk about. We want this program to be very objective, as objective as we can get. So there is certainty, there is something that people can hang their hat on and also give everybody the same confidence.

Transparency is one of the key things that we're building into this, that we know, the community knows that when products are transparent -- the community knows how the product is performing gives comfort to people who are making these products.

And I touched upon the last thing about learning and adapted. We will, as we think about this from an agile perspective, and you'll see me using these terms over and over again, we need to iterate. We need to sort of make sure that we're not stuck in one spot. We need to iterate, we need to learn and sort of move. And that's an adaption that needs to happen. And it should apply to even regulatory

programs. And that's what we are trying to shoot for.

Here's an ambitious goal for all of us. So from here on it's not what FDA needs, it's what we need as a community. That's really what we're looking for. So every time I can tell you like when we visited the nine participants and the question was what do you need? And my response always was let's figure out what do we need as a community to build a system. And how do you sort of make sure that we have the right parameters in place so we can do this?

We are hoping to by the end of this year to get to a minimal viable program that we can then move forward next year. That's the idea. I'll show you why I say that, why this is important. I think it's important for us to sort of start thinking about building these components one by one. And I've broken it down into three big things. And I won't read the rest of the slide. This is just for a reference. But we need to figure out what the excellence appraisal looks like. We need to figure out what the streamline review looks like and then figuring out the last component is like what's the post-market world and

access to information looks like that will give us confidence. These products are actually working in the way that we intended to.

We are here. We are in the beginning of the process. For the last to four months we have been trying to figure out what is the right vocabulary? How do people do business? How do people, good companies make products and sustain them in the marketplace? What should those characteristics look like? We have been spending all of our time, and you'll see the materials that you saw in your packages and you'll see that tomorrow as well, is we have put in a lot of work. And the team has put a tremendous amount of work to sort of try to figure out a way that aligns vocabulary to business vocabulary. Try to minimize the translation cause between what you do as a business to what we need as a community to show that confidence. That's exactly what we're trying to shoot for.

So just to orient you that we are in the very first step of the program and by end of this year, don't be scared, we will try to build -- we'll build a minimal viable program to the entirety. We will get it

right to some degree. We will get it wrong to some degree. The key point to take away is we need your help and input to build and to make sure that it's getting -- we it right. So this is an opportunity for everybody to sort of chip in and help out and that's where we want to be.

Let me take you through the journey of how we've spent the last four months since the announcement of the program. We started we announced the program in July. We asked for people to join in and help us build the program. We had a tremendous response. I am very thrilled about that. We picked nine participants representing a very broad spectrum from an extremely small organization to a larger organization and everything in between. And we looked at different aspects, as well as where they are in the ecosystem, where they are from what kind of products they make. So we took that carefully, given the bounds we had of nine, we picked as carefully as possible so the spectrum we can choose from.

And we've spent the last four months, actually, the team spent, including me, spent seven

weeks talking to each of those nine participants. And you will talk to the nine participants and you'll realize we evolved and iterated every time. And the iteration continues to happen going forward. And that's the thinking we are going into.

We started off with the five fundamental principles. I want to spend a little bit of time on this one just to make sure that we are aligned. These five principles, our core we thought are important for assuring a high level of quality in these products they're making and organizations that are making these products. We want organizations to be focused on patient safety, keeping patients in mind. We could argue here is it consumers, customers or users? It's really all of the above. We can talk about that and say if an organization is completely committed to their customers, to their users, to their patients we want to see that. What does that look like? We didn't have answers to like what that criteria is and that's what we are building.

Let me take the next one, high product quality. I would say that's been a fundamental thing

that we need to sort of focus on and say if we find excellence in driving high product quality, we want to see that.

We want to see people having clinical responsibility. Which means that everything from research, to trials, to making sure the right level of information is presented and how it's presented to the patients, and making sure that users know exactly how the clinical performances go, including the evaluation.

Need to be cyber responsible. We know it's an important emerging area. We need to make sure people are prepared, this ecosystem, this sector is prepared for that.

And last, but not the least, it may seem kind of odd why is on this slide, it doesn't kind of fit in with everything is the culture. And I'll tell you one thing we learned over the last four months and we've been talking about this is the culture. We want to make sure that there is a proactive culture through organizations embedded and threaded into every employee, everything that you do inside the organization.

So we started with these five, these principles and said let's try it out. And we -- I can tell you that talking to all nine participants and other stakeholders we found that this is something that people said, yes, we absolutely want to see. The details are important and we needed to make sure that let's go figure what those details should be. So that's the starting point.

Let me take it one step back and sort of say how we have been doing this. We have been iterating on the process itself. We have been iterating on how we approach this. We have been iterating on how to present it. We have been iterating on how to ask the right questions. Again, a test to you people like did you really mean that when we had the visits with the sites? And every site we had a different experience. And I think we've learned. And that's the momentum we want to keep on.

Here's what we have been doing. We started off with one level down, like how do you identify those things that follow excellence principles? And we came up with this vocabulary of common validating

perspectives. But really embedded in those were the things that we always looked for is leadership, strategy, you know, practices, policies, partnerships, etcetera. We were not very explicit on that. And we thought keeping it simple was important. What we found out really quickly is the vocabulary and how we present it is going to be important as well.

We got the input and you can see the iteration model here. We got input from the site visits. We also independently did a review of sort of what exists out there. And you'll see today later on how other industries and other sectors in the world have called, they have been evaluating people from excellence perspective. And we want to learn from what's best out there. No point in recreating the wheel if it's already been created. And how do you sort of line that up?

The next day is all about you. The next two days is all about you. So we are at the next point. This is the workshop we want your input on. We'll be sharing with you what we have found so far and what we have collected. And how do you sort of take that to

the next level? So help us do that.

This is the literature review we did and we looked at different models and said if you look at different models and said if you look at what people measure excellence from it does exist today from other areas. There is a CAnandian model, there's actually an Australian model and then there's Baldrige that's in the US, very prominent. How do you bring that together?

This slide is just for to know, just to show you that the vocabulary is important. How people see this is important. And we are trying to align to that. So instead of looking at what we started off with, we are now actually evolved to a point where we're saying I think to scale from a small versus larges organization it's important to talk about the leadership strategy, partnership, the resources and people. And then matched with the outcomes and the results that they see as an organization. So we've been sort of thinking about that evolution. And you'll get more details of this as the user or go to the

workshop. We also published a paper that you guys should probably look at, sort of the journey of what I'm just sharing today.

So we are here today. I'm going to share with you what we learned from the pilot participants just to get everybody on the same page. And this is going to be about setting the stage going forward. A few things we wanted to confirm and understand. What, when we talked to the pilot participants, what did they want? What do they see the vision of this to me? And truly back to this notion of building this collaboratively with everybody. We had our own objectives and goals. This is where we found out we were not so far out of sync. We are very much aligned with the nine participants where this program needed to be.

And you can see the shared results of vision is about high quality product without compromising safety and effectiveness. There's nobody I heard or talked to said we need to do something differently here. That's a consistent messaging. There is always details in terms of getting faster to market. Of course we want it to faster to market. It's about

making sure that we all understood.

I encourage everybody who has been thinking about this and have questions to talk to us, understand what we are trying to shoot for. And this is something that is really important for us, for you guys to contribute and help us. We don't have all the answers, but we have the same goals. We have the goals for the program to achieve and make sure that it is achieved by your input.

We are looking forward to engaging you. And you guys may have heard me talk about this, you are the tenth participant. The public is the tenth participant. So if you think you didn't get part, chosen to be part of the nine participants don't think that way. You are the tenth participant. We want your input. And this is where you can add and inform us as we move forward.

Here's what we've got affirmed as well. These five principles we started off with I think everybody understood very clearly that's a good goal to have. And it's going back to the shared vision that I just talked about. It's important to make sure that patient

safety, produce quality, etcetera, was something that you see is important to be in an organization. So that's something that we've got affirmation.

Here's what we sort of also saw questions come up. People were fast-forwarding and figuring out like what does that mean for a 510-K? What does that mean for something else? What does that mean for things that we do today? And a lot of time was spent to figure out how do we take a step back and figuring out what is the right way to do things? So this is really about reimaging. And in the software speak it's refactoring our regulatory system. How do we refactor it in a way that actually will be efficient and beneficial for not just for the companies, for all stakeholders? For FTA, for companies, people who are making products and patients at the end of the day to the true North Star, as Jeff talked about.

So let's talk about what we learned. So this is just a snapshot of what we sort of synthesized from all of our site visits. We had lots of data and lots of observations. And we talked to folks. We spent entire days talking about processes. We spent entire

days talking about how people do business, how they've actually developed the products. But we satisfied these traits.

There is a strong leadership component that we saw that was important in all of these organizations. I won't read all of these bullets, but let me just touch on a couple things. Core values within an organization was completely embedded in every employee. And there was efforts made by leadership to be -- to continue to sort of have that message going on.

One thing that kind of stood out for me is the integration of processes that existed across the entire organization, which was very important and interesting to sort of see. And that led to many things, open communications, leadership knowing, and everybody in the organization being able to share information at any given point in time without hesitation. That was something enabled -- using, again, using technologies to sort of build that culture was something we saw.

We also saw that people spend a lot of time actively engaging their stakeholders. When I say stakeholders I mean really broad. They're users,

they’re providers, they’re ecosystems, where the products are going to live and how it’s going to be used. It was very well thought out. We thought it was important for people to sort of have product launches. We also saw product launches were very closely managed. And in the space with that feedback mechanism that is available in the world of software it was important, an importantly used tool in a way that actually helped people to sort of stay on top of how their products were doing, especially in the early release days. So that was something that we sort of stand for us as well.

And last but not the least, this is something part of every quality system that we think is important is having the right people. And when they’re identifying having the right people, identifying when we’re not, when there’s not enough people, seeking out and making sure stakeholders are engaged was important. Something we saw for all excellent companies. So just a highlight of what we saw.

But let’s just switch gears. So this is where we stopped and we consolidated. We wanted to prepare

for this workshop. What we want to do in the next couple days is, one, today set the stage of where we are today. So this is the beginning of it. You'll hear from the pilot participants and then from the FDA staff who joined me at the site visits to sort of hear their perspective. And this is an opportunity for you guys to ask questions. But we'll probably do today look at engaging you, answering your questions and making sure that we are all on the same page going forward. And I want at the end of today for you all to be as excited as the pilot participants and as we are to help us build this program.

So today, as Marisa talked about quickly, we are going to have five panels. And you'll see those from the agenda. We start form the top, dive down into a little bit more detail and at the end we will look at other models. Because we do want to try to solve and sort of look at how do appraise and identify and recognize excellence? We want to make sure that happens.

One thing I do want to mention that I should have in the earlier slides about goals, we want to make

sure that we give credit back to those organizations who are doing the right things. Which means that if you already are doing the right things we should be able to recognize that and we should be able to give you credit for that that sort of aligns to those five excellence principles that we talked about. So how do you do that is something that I want you guys to help us build it.

We have three breakouts tomorrow. And the design of these breakouts is to make sure we get very tangible inputs, so that it informs the next steps for this program. So breakout one is all about understanding, what are the things that we pointed out this morning from what we learned should be added to this? Help us build that framework, what that looks like from the enablers, is what we call them. What does that look like from outcomes that we should be looking for? And again, back to recognition of what that looks like.

And then last is about how do you present this information that we all can sort of be transparent about? And that gets in a discussion about score cards

and dashboard. So how do you get there? So we are going to dive deeper than this high level talk today to the next level and being really technical. We need to do this because, as you saw, some of the discussions and some of the goals that we have for the program by the end of the year we need to sort of create a program that we can then now start actually start figuring out how to appraise a company, review a product and make sure that we have the mechanisms to understand what the post-market data looks like from a real world perspective.

So here's my ask, engage, engage, engage. We have avenues and we have been thinking really hard how to engage you guys, everybody in the community. And the progress we are making, so this is sort of our first engagement, public engagement we are doing today. We have been doing webinars, but it's not as effective as being in person. So we have put out, we have an email address. If you have questions about the program don't hesitate to ask. It will not only inform us about the questions and the things that you care about, but also inform us like what do we need to solve? What

do we need to solve going forward?

Number two, we have been putting updates on our website. I know it's not probably the best tool to sort of put in this day and age, but that's what we have. Please look at that information that we're putting out. I think that's an important source of sort of avenue for you guys to sort of see where we are. And help us build the program by submitting your input to the docket itself directly. You can always talk to us, but I think the docket is the most important mechanism for us to sort of get information back to us so we can consider it into building the program.

Again, I encourage everybody to be collaborative here, provide your inputs. Like Jeff said, no idea is a bad idea. We will take all of it. And, again, there's no presumptions here. So we are actually trying to build it with you guys. So if you think this is something we already have set in mind, no. We are looking for the right answer. We don't have an answer. We need to get to the right answer.

So with that I'm going to turn it back to --

oh, I think I'm staying up. Sorry. So with that I'm going to have the pilot participants join me on the stage and we'll jump into the panel. Thank you.

(Applause)

MR. PATEL: So I guess I'll sit down also. So we've put this panel together for a couple reasons. We spend a good two days with each one of you guys. And the idea for this panel was to share what you guys took away and how you saw this program evolve. So I'm going to start with asking you a couple questions. But maybe before we do that I think people will appreciate just briefly just walking down the line and saying who you're with and then what your role is.

MS. MILLER: Hi, I'm Danelle -- is this on? Hi, I'm Danelle Miller and I'm Vice President of Global Regulatory Policy and Intelligence for Roche Diagnostics.

MR. PATEL: Okay.

MR. LOOK: Hi, I'm Howard Look, I'm the Founder and CEO of Tidepool. We're a small startup in California. I'm also our head of regulatory and quality NRVP of HR and I clean the fridge sometimes.

(Laughter)

MR. LEE: Hi, I'm Yong Jin Lee, I'm the Senior Vice President at Samsung Electronics. I am responsible for the digital health devices at the company.

MS. JOHNSON: Diane Johnson, Johnson and Johnson. I'm the North American Regulatory Policy and the Digital Health Policy Lead.

MR. CARRIER: And Larry Carrier, head of Regulatory Affairs at Verily Life Sciences.

MR. BISIGNANO: I am Alex Bisignano, I'm the Founder and CEO of Phosphorus. We're a small genomics company based in New York City.

MR. PELLEGRINI: Adam Pellegrini, General Manager of Fitbit Health Solutions.

MR. ARMOR: David Armor, VP of Quality [and] Regulatory Affairs at Pear where I work on prescription digital therapeutics.

MS. NEWBERGER: Jennifer Newberger, I'm the regulatory team at Apple working on the health projects.

MR. PATEL: Great. So why don't we just

start, I'm going to ask a couple questions as we talked about in our call earlier. So, Danelle, since you're sitting next to me, why did you decide to participate in this program?

MS. MILLER: You know, I think as Jeff eluded to, you know, decades old regulatory paradigm just did not contemplate the challenges that we see with the rapid innovation and iterative nature of software. So the precertification pilot to us was the first step in trying to find a more fit for purpose regulatory paradigm.

So with us we looked at it and we said, okay, Roche is one of the leading IVD manufacturers. We do innovative software. We bring a unique perspective that compliments the others. At the same time we're very interested in, of course, where the regulatory paradigm goes.

MR. PATEL: Okay. How about you, Diane?

MS. JOHNSON: There were several reasons. The first is J&J has been for years now looking at a comprehensive digital strategy delivering total patient solutions leading to improved patient outcomes. I mean

frankly the software review process was not really in line with that goal. So getting to a more right sized quality system approach, we were very encouraged by that concept. And being able to, as a very large company with a lot of smaller companies in it, being able to come at it from kind of a company level across pharm, consumer, devices, how do we provide these total patient solutions across the entire company?

MR. PATEL: Thank you. So I'm going to turn to David and see, you know, David you have been sort of helping and guiding people before you joined Pear Therapeutics. And you obviously knew a little bit about FDA, quite a bit about FDA and helped people through. So what were your expectations getting into this program? And in your role at Pear, how do you see the sort of the advantages are beneficial to your company?

MR. ARMOR: Yeah. I think there's always a certain level of formality expected with FDA interactions. And one of the first things that, you know, set the expectations with the program was that. And I think we were pleasantly surprised and really

encouraged by the fact that this truly was FDA rolling up their sleeves with us at the table and working collaboratively. I think that term collaboration it's not just lip service with this program. It truly was something that was, you know, folks like Bakul, folks like Cathy, folks like Marisa and other folks in the room on the FDA side were not just, you know, tell us what to do or here, we're going to tell you what to do. It was more, "Well, what do you think about this? And how do you approach certain things this way? And what kind of approach do you use for cyber security? And all these different aspects of the software development life cycle. So it truly was collaborative.

And, you know, for somebody, you know, within a company, and much of you folks probably understand this as well, where a lot of folks in a healthcare company, a digital health company don't necessarily have a healthcare background. There are a lot of them that come from consumer health products. Having -- being able to say, hey, we've got to look into KPIs because FDA is telling us to do so. "I'm sorry, like, we've got to do this, you know, homework." And, you

know, Bakul is telling us, “Sorry, we’ve got to do this.” It was really a good opportunity for us to learn together through this program. So --

MR. PATEL: Building on a KPI exercise, I’m going to ask Jennifer to say how did you see that exercise? I know we started off and we evolved. By the time we got to you we had already seen like five companies and we were already like standing or were thinking. Can you share? And then I’m going to go to Howard next.

MS. NEWBERGER: Sure. So, I mean, it definitely made us think about how we do things in a different way. I mean we don’t, you know, I don’t think that we think about KPIs in a traditional way the way that other companies might do it. And so it sort of forced us to examine what we do, how to make it useful, how to put it into a way that would work for purposes of this program, for industry as a whole and learning through that process and learning from the other teams at the company.

MR. PATEL: Yeah. Howard, do you want to add to that?

MR. LOOK: It was a really amazing process for us because, as you know, we went into it and when I looked at the original set of questions that evaluated along the excellence principles and common validating perspectives I was like, what, this makes no sense. We don't think about it that way, we think about it this way, and came up with all the different questions.

And when the FDA came and visited us, to my wonderful pleasant surprise, you and your team were all like, "This is awesome. Let's dive into that. Let's actually understand how you build your software and what things you do look at in order to convince yourself that you're building safe and effective software and delivering processes that improve over time."

And the act of cracking that open actually made us realize, you know what, there are some ways to look at KPIs in here. We can, for example, look at the way we evaluate risk and the way we evaluate bugs and say, for example, are we reexamining things that we've looked at before? And let's count up how many times we do that and decide what we think is an acceptable

number. So that co-creation and collaboration process with the team really helped expose that there are lots of ways of building high quality, safe, effective software. And it really can scale from a small company like us, with 13 employees, to some of these bigger companies. So it was great.

MR. PATEL: Yeah. So, Larry, I mean we spent -- you were the first site we visited and we totally experimented on you.

MR. CARRIER: Yes.

MR. PATEL: Do you want to share your thoughts?

MR. CARRIER: And we appreciate that. Yeah, it was, I mean, it was a great experience over all. It was very challenging. I mean one of the reasons we got into it was just to be part of something new. I mean I've never seen an initiative like this at FDA, at least in my career, where you get to kind of building something from the ground up.

So, yeah, we were the so-called guinea pig. So, well, you guys too. So if you can imagine a bunch of little guinea pigs standing and someone with little

FDA badges ready to jump in. So there were times where there was, you know, awkward silence. We would look at each other across the table kind of, you know, wondering kind of where do we go from here?

But overall, yeah, I think it was, you know, a lot of self-reflection about what do we do, why do we do it, how do we know that we did it well? I think those are some questions that you, you know, typically go about your daily life or at work and kind of don't ask yourself about. So, yeah, I think overall it was challenging.

I mean at times it felt, and I think you eluded to this and Jeff too, like you know, we're kind of flying the airplane as we're building it, which can be a lot of fun. And it was. But, yeah, overall I think we're always moving forward. And hopefully, you know, I think being the first some of that was helpful going forward for some of the other participants. So --

MR. PATEL: Yeah, it was very informative. Like, actually, we learned quite a bit. I mean we didn't even ask the question about what Larry was

talking about, is he said, you know, “Tell us what you do?” And then we heard what they did. And then we asked the questions, like, “How do you know that you’re doing the right thing and how do you know it’s actually working all the time?” And that raised a bunch of questions going forward. And that was -- and unfortunately we did it on the second day in a level setting. So it was the flip that happened after the very first site visit.

MR. CARRIER: Yeah. I mean one thing that’s come up a number of times, which I think is challenging too, is just the language.

MR. PATEL: Yeah.

MR. CARRIER: You know --

MR. PATEL: Vocabulary.

MR. CARRIER: Just getting on the same page with some of the terminology and all that. But then at the end of the day we can kind of call it whatever we want. I think you have to have something to anchor on. But some of the terms and terminology, yeah, were just somewhat kind of foreign with respect to --

MR. PATEL: Right. It’s not natural for a

business to put their -- align themselves to. So, Alex, I mean we had a very interesting conversation at your site. And you had a very interesting perspective on transparency. Can you -- would you mind sharing some of that?

MR. BISAGNANO: Yeah. I think it was, first, a great experience to work with you and your team. I think for us it definitely opened up some thought processes around our processes and, you know, deriving KPIs from things that were kind of institutionalized at what we do. Transparency is a big theme for us, both within our industry, genomics, I think is undergoing obviously such transformation. And there's such a diversity of practices that need more transparency.

But within the organization I think one thing that we showed was a lot of how our development processes do span across the company and allowing everyone to see as much as we possibly can, I think, creates opportunities for more quality and for more measurement. And I think teasing that out with your team and figuring out, all right, maybe we are measuring something, but we didn't know we were

measuring. It was actually a lot of fun.

MR. PATEL: Yeah. And now, Jin, at our site visit we spent a lot of time thinking about, I mean, Samsung is really rigorous in terms of like know and coming from a manufacturing background you have those things completely, like, mapped out in other parts of the business. And so we spent a lot of time talking about sort of translating it to the world of software. Do you want to share a little bit about that?

MR. LEE: Sure. Yeah. So in terms of, I guess, the five key metrics, there were three areas that we were very comfortable with within the mobile division, the product quality, cyber security, proactive culture, reaching out to the end users, being able to take information as quickly as we can in adapting our product. So I think a lot of the discussions were around how do we take that and apply that towards theSaMD?

And I think the other two very critical components, the patient safety and the clinical responsibility, while the mobile division don’t have direct experience with it, Samsung itself we have -- we

operate a hospital, we have Bioepis, we're one of the largest biopharmaceutical companies. We have a teaching analytical school. We have a medical equipment division. So we kind of inherited a part of that culture. And what we wanted, I guess, to do was maybe take our direct experience for product quality and the kind of the experience that the overall company has in the clinical area, then try to focus that into the SaMD.

MR. PATEL: Yeah.

MR. LEE: It was a very interesting discussion, I guess.

MR. PATEL: Yeah, we were learning together. So, you know, Adam, I mean we had a great two days as well. And we started off thinking differently. And you guys spent a lot of time, I know, we challenged you saying if you were to do it yourself, how would you do it? And we ended up talking about different ways you can sort of line yourself up to the five principles. Do you want to share like a couple thoughts on like how you took away the two-day meeting and what you got out of it?

MR. PELLEGRINI: Yeah. I think what I like is some of the key words I've already heard. So things like breath of fresh air, co-creation, these are things that were immediate takeaways after the two days that came to my mind. And I think coming into it what was probably the most difficult, and you had mentioned challenging, one of the biggest challenges is suspending preconceived notions of what this is going to be.

And I think through this experience the open dialog was, I think, the most amazing part of the entire two days. Truly, you know, suspending those, again, those preconceived notions of what this engagement's going to be and co-creating in a co-creation process. That's something that I think for those that are, you know, we have those folks from other companies and that are medical devices, so really sort of setting that new groundwork of this is the way things need to work in the future. To me that really did speak to the innovation of this process.

I really came away with just nothing but incredibly optimistic impressions of the precert

program. And really it made me just even that much more a champion of this type of way of engaging, you know, the FDA in the future. So I think lessons learned from me and our team was really ask questions and listen and engage in the dialog.

Like what you said today of the tenth participant, ask as many questions as possible because that's actually what got us over the preconceived notion hurdle those two days, if you remember, is really just asking every question we possibly can and getting the answer. And then from there on I think it was massively productive.

MR. PATEL: So I'm going to turn to Diane and Danelle again and ask them what questions, I mean you come from a regulatory background, what questions do you have that got answered and what's something that you want the audience to hear?

MS. MILLER: Well, first of all, I will say I was glad that they started with somebody else to work through some of those things because it was great by the time it got to us. You know, I think the main thing for us is, you know, as a device manufacturer we

came in quality system, quality system, quality system at the top of mind and that's our language. It was, for us, it was much more, ah-ha, it's organizational excellence. Which is not throwing away quality, it's still very much you've got, you know, product quality, patient safety, etcetera. But it's taking that level above. It's a threshold above just basic compliance, but truly organizational excellence. And I think that was probably the most important part for us.

MR. PATEL: What about you, Diane?

MS. JOHNSON: So I guess my ah-huh moment, which is very closely related is we weren't looking at what SOP supported what section of the reg. We were actually looking at how do we know we're doing the right thing? So at J&J we have the credo and actually got credit for it. The one question that we didn't really get into that we probably as an organization needed to understand better is it seems like a right sized quality system is definitely an option. And we don't have to try and stuff software into the classic design history file approach. And, you know, we really are as a company very interested in shaping what these

sorts of things look like going forward. But then, of course, the question comes around back to what about the enforcement arm? So that is probably the one thing we didn't ask that we should have or wished we had.

MR. PATEL: So we don't know answers to those, right, and we need to figure out what's the right enforcement level and what's the right metrics and all this stuff. So, Jennifer, I mean we had a bunch of discussions about -- and you heard me very strongly mention to stay off certain boundaries. Do you want to share some of those?

MS. NEWBERGER: Sure.

MR. PATEL: Jennifer and I go -- I mean she was working in CDRH, so I can talk to her like this.

MS. NEWBERGER: Yeah. So Bakul and I go back a number of years. And it's not, of course, common in Apple culture to talk much about anything that we do. But I can share this. So, yeah, Bakul and I got into a discussion on the second day design history files and part 820 and sort of the questions of, you know, is what we are creating basically just another 820, you know, by a different name. And sort of if we're

creating something that will be potentially more burdensome, like what's the utility, what's the balance. And Bakul was very clear that he did not want us thinking about 820, talking about 820, trying to relate this to 820. But, of course, for all of us at the table who that's, you know, that's how we've grown up, that's what we know and that's all of our training and experience. It's hard to really separate those two things out. But I think what we got out of that discussion was that, you know, there really is a genuine interest here in creating something that is specific to the situation. That it isn't taking what already exists and tweaking it slightly to make it work for software. It's really trying to create something new for software at the pace at which software develops. So I think it was a useful conversation.

MR. PATEL: So I'm going to turn to Howard because Howard has gone through this journey. And Howard and I also have discussed this a few years back. So, Howard, do you want to talk about starting where Jennifer leaves on that topic?

MR. LOOK: So I probably come -- we're

probably digging the tunnel from both sides of the mountain and meeting somewhere in the middle. Like I come at it from a Silicon Valley software entrepreneurial perspective, not from a medical device or regulatory perspective. And so when Tidepool started doing this I actually knowing that we were going to build what at the time was class three medical software, eventually got reclassed, thank you, to class one exempt, we had to understand all the regs. And it just honestly made no sense. And I remember having a conversation with Bakul early on and I was like, “We’re building this quality system and we’re building software the way companies Silicon Valley build software. We’re using test automation and we’re using Trello and Slack and GidHub and Google Docs. And let me show you everything that we’re doing to build our software in what we believe is a high quality software way. But there’s one thing, this design history file.” And I showed him this crazy spreadsheet we had built and Bakul said, “Well, why did you build that?” And I said “Because the regulation said I had to.” And Bakul said “Do you ever look at it?” And I said, “No, never.

That’s not how we build software. I look at our test automation results and continuous integration. And we look at our bug reports and this is how we do it.” And for me that was an epiphany where Bakul was basically saying, “Look, we want you to be building software and running your company the way that makes sense. And we want to know how you think about delivering high quality, safe, effective product.” And so thanks for that.

MR. PATEL: I just want to make sure that people online are able to hear and too able to ask questions. And folks in the room I think if you have questions, I mean, please make sure you’re writing on your post -- on your notes and forwarding it to Seth who is going to read out for us. So there is a question. Where are you going? Oh, there’s no question. Okay. Oh, you’re saying hi. Okay.

So folks who have questions during the discussion please feel free because we want this to be not just us discussing here. I think the intent for this panel is to clarify certain things you’ve been thinking about or questioning about and we can sort of

answer that as well.

AUDIENCE MEMBER: Can we ask questions here because we don't have sheets to write questions on, is that okay?

MR. PATEL: Oh, yeah, sure. Go ahead.

AUDIENCE MEMBER: Wonderful. Thank you so much for your very lively discussion. So two questions and they're kind of related. So to introduce myself I am a professor at Johns Hopkins University in computer science and (inaudible) policy, my expertise is in machine learning; we've developed new tools using machine learning for driving decision-making at the point of care.

So the two questions, the first question is I think machine learning (inaudible) at a very rapid pace in a way that some of these organizations (inaudible) and they're active researchers who run (inaudible), you know, the notion of like, you know, the notion of like adversaries and fault tolerance, and reliability, and notions that we're discovering as we go. And I think it would be useful, it would be exciting to engage more of academics in this space as more and more digital

(inaudible) going towards data-driven tools. And to be able to inform decision-making that may or may not be coming straight out product-driven tools. So that's one idea.

And then the second question is you mentioned this organization of excellence. Can you talk about how you measure organizational excellence? Like there is a notion of best practices and (inaudible) machine learning in the software. Who defines the standard, how do you define it. Do you jointly discover it, together?

MR. PATEL: Yeah, so --

AUDIENCE MEMBER: Especially in areas that are (inaudible) transformed.

MR. PATEL: It's a great question. I think that's exactly the journey we are on. We don't have an answer and this is why we are asking everybody to build. So I'm going to see if anybody wants to answer that because I have said it to you many times, like what's the answer for if somebody's looking for an answer from you guys what should we be telling them to help us build that, right? So I think the question is

like participate in it tomorrow. Help us get to the right excellence level. And it's not about -- it's less about what tools and techniques you use as it is about do you have the right way of doing and having the right culture in place. So thank you for those thoughts, I think that's really, really helpful.

Let me just, I don't see anybody else and if there's nothing online, let me just go onto a question that sort of we had put together and said, you know, what really surprised you of the process, of not just the site visit, but just the process itself of the precertification program? What does that sort of said to you like, hum, that's interesting and I have not have thought about it? So I'll just start with Jin and then maybe I'll go to Alex and Adam.

MR. LEE: Yeah. I think the process during the site visit one of the things that really struck was how FDA was really open to making very fundamental changes to help the industry. And we were very happy to see that direction and the change.

In terms of surprises, I don't know. I guess a lot of us kind of had a traditional view of the FDA.

So kind of a premarket relatively conservative and was to see this willingness to change and help industry and the digital health space. That really was very --

AUDIENCE MEMBER: Speaker louder.

MR. PATEL: Oh, yeah.

MR. LEE: I'm sorry. Yeah. So I guess the willingness of the FDA to adapt to the change in the industry, to adapt to the direction the digital health is moving was really a good surprise to us.

MR. PATEL: So, Alex, do you want to touch about how we describe the program, the picture that we had, the concept that we drew out from, you know, certifying and then using software as a medical device. What in that entire process, what do you see different and more surprising for you there?

MR. BISAGNANO: Yeah. I mean I think it's obviously been mentioned before, but the level of collaboration and cooperation here is very, very evident. And I think one of our concerns of where it could have gone was, you know, just another SOC 2 or another CLEIA requirement. And I think I definitely left the two-day site visit, actually, I think many

times you and your team had said “Stop, you’re talking compliance language. Please start talking, you know, results and KPI with us.” And I think constantly bringing it back to the real tangible value that the business is producing sort of abate all my fears that this is just another kind of set of paperwork that we need to get through. And I think that’s really, really valuable for what this program can become.

MR. PATEL: So, Adam, if you were to tell the audience or people who have not been part of the journey with us and maybe I’ll go to David next, is what would you tell the audience that they should stop worrying about?

MR. PELLEGRINI: Well, I think first of all that this is not about a product or products getting certified, this is about the building of a process. And I think when it goes back to surprise we weren’t sure if this was going to be, oh, it’s going to be about a product, whereas, product you’re going to put products through this. But really finding out that it is about building and co-creating the process and that the process wasn’t going to be the measure, but the

outcomes were going to be the measure. I think that is something that everyone should be really focused on. Because in this age of healthcare, especially in digital health, I know we're all very focused on outcome driven everything, right, business models, KPIs. So the fact that the digital health FDA process was actually a framework that would actually have outcomes driven metrics that are asynchronous in nature, that we stay connected past these sorts of engagements.

And I think that's the other thing that I would say is this is not about a one and done. We all, you know, shake hands and say this was fantastic. I know we had great dialogs this morning about this. This is about, you know, you go through this and then you are now connected in a relationship, a partnership has developed with the FDA. And I think that should be, again, a breath of fresh air. And that the dialog can be free and can be open. And I think those are not just surprises, but delights about this process. Now, clearly it's a starting point. There's a long way to go. I mean this is the next step, this event or this

workshop. So after this I think the whole ten participants will have their own insights and observations for the next event. So that's at least my takeaway and some of the surprises, delights and expectations out of this event.

MR. PATEL: David, do you want --

MR. ARMOR: Yeah. I think I had two key takeaways. And I'm glad some of the other panelists echoed the sentiment that I think everyone else should extract. It's that critical that I'm going to say it for the sixth time, I think. Where, for example, I think the sixth or seventh time Bakul heard the term 510-K, I believe you threatened a swear jar at some point saying that if, you know, if we said that again we were going to have to put some --

MR. PATEL: And it did happen.

MR. ARMOR: Yeah. So I think that's the first key takeaway. I think, you know, what resonated with us actually prior to the meeting was something Marisa actually said, which was let's strip away all the regulatory aspects. If you were a patient or a provider and you were selecting a piece of software

what would instill confidence in that software provider for you personally to have to review, right? So what about that company would instill confidence in you as a receiver of care as an HCP in order to say I feel confident using this? And I really resonated with this in terms of restricting this framework versus, you know, presubmission and premarket notification and the QSR versus what's the actual intent of this.

And that really kind of segues into the second thing I think folks should not be concerned with. So at Pear we're really intentional, we've intentionally and purposefully sought out clinically validated software applications. So I think we look at things like, you know, prescription digital therapeutics as a class of product with clinical data, with clinical support. And we're going to be on one side of that spectrum of the precert. But I think one thing folks should take away is that they shouldn't be concerned that precert means, you know, automatic granting of the equivalent of a marketing authorization or, you know, I think that's something really key. That there still will be a tiered structure or tiered segmentation based

on risk and other inputs that will allow, you know, like Dr. Shuren was mentioning, that will allow products that require clinical validation that are a little bit higher risk to continue to do so, just maybe in a different framework. So I think those were the two key takeaways for us.

MR. PATEL: Great. Jennifer, did you want to add something to that?

MS. NEWBERGER: Sure. I mean I think honestly one of the takeaways for us was actually like an internal takeaway. It was like how excited people were to actually have this opportunity to engage with FDA. Again, not something that we're used to doing. And sort of watching this shift from when I would go sort of talk to people in the different teams to say like, you know, "FDA's coming in and we want to be able to show off what we do." And the response was like, "Oh, that's where we tell them all about everything that we do." And it was like not said in a good way, but sort of why are we doing this? This is very, like, not the way we are used to operating. And watching that shift, it's like some of the people who had some of the

longest presentations and the most Q&A were really very doubting, I think, of the process at the beginning. And so just seeing that, seeing like the high level of, you know, executive involvement, folks who came, folks who sat through two days when they obviously had many other things to be doing. I think for me it was a great buy in process internally at the company to be able to move forward through this.

MR. PATEL: We'll take the question from on the web and then I'll turn it over to Diane and then we'll talk to her.

SETH CARMODY: I have lots of questions now.

MR. PATEL: You going to answer to them too?

SETH CARMODY: I (inaudible) the people (inaudible), so whatever you want.

MR. PATEL: Do, go for it.

SETH CARMODY: Online question for the panel. How are investors looking at this particular program? It's saying something about health (inaudible) organization as opposed to health products. Does anybody want to comment on it?

MR. CARRIER: I can make a quick comment on that. Yeah, once the participants were announced, yeah, we got -- we started getting a lot of calls from our partners saying, “Hey, how quickly can we get our device?” And, know, if they were collaborating with you into the program. So there was level setting. That word ‘pilot’ in the program, it’s not actually a pilot yet. So there was, yeah, there was a tendency for folks to, you know, look that, oh, this thing has already been built and these guys are going to be submitting their devices and we want, you know, we want to be part of that.

So I think there was, at least with our partners, who are mostly our investors as well, there was just some level setting there to really describe, okay, this is what the program is and this is what we’re doing. And then there was kind of an ah-ha moment where they said, “Ah, okay. Now we understanding this is going to be a process and this is going to happen over time.” So thank you.

MR. PATEL: Howard, what do you think your answer would be for that? I think the question is, you

know, how would investors look at this. And you've been in the startup phase and been around Silicon Valley for a while. So --

MR. LOOK: Yeah. Well, so Tidepool's a little interesting because we're a non-profit, so we don't have any investors. But we --

MR. PATEL: This is why I asked you.

MR. LOOK: Yeah. We're -- but our donors thought it was awesome. And we got a little bit of the same thing too. We would get reporters calling and saying "What's the product that you got certified for?" Like, "No, that's not actually what happened. It's a pilot program and we're working on the process." But being in the space and living in Silicon Valley like I think the biggest, maybe connecting this to the last question, the biggest ah-ha when I would talk to people in that space is, look, the FDA is acknowledging that the old method for an organization whose job is to protect the public health and safety, and Dr. Shuren got to this earlier, it had a little bit, or maybe even a lot, of an unintended consequence, right. It caused investors to say, you know, I'm not sure I want to

invest in that new innovative therapy. Or it would cause a little startup like us to go, you know, that's more trouble than it's worth. We're going to go do something else. And so this is really revolutionary.

I blogged about this recently, right. Like when this really happens what it means is more and more companies and more and more investors are going to say this is awesome. Let's go do something totally groundbreaking, earthshattering, innovative that is going to be of benefit to the public health. So to me I think that will be the greatest outcome of this program.

MR. PATEL: Great. We'll take a couple others.

AUDIENCE MEMBER: Yeah. So a couple of themes that I'm seeing here and that is a lot of questions here. What about day-to-day operations? Like I'm submitting IDE submissions promptly, you know, how does this program impact those things that are going on right now or things that may be planned (inaudible) ahead?

MR. PATEL: So I'll touch upon that because --

AUDIENCE MEMBER: That's probably a guess, yeah. So I can tell you like, look, in the world of software when you think about refactoring you have to live in this world where there is things happening in parallel. We are trying to learn just like people would do normally, if people are working through IDs and their current submissions we want to learn what the inefficiencies are. And from that process try to figure out how we can sort of get the program to be in the right spot.

We will be partnering with the nine participants here to try what those things are and what those instances where you need to be -- that's something that we can sort of understand where the issues are and try out how we can -- and take that input into the program. So I think nothing changes at this minute for those existing submissions and people who are going through the process.

What we want to do as part of the pilot -- and it's not a pilot, right, so it's a development of the program. We didn't have a different word, so we used the word pilot. But in the process we want to learn.

So we will be looking at, you know, experiencing what the experience looks like for the program itself in different parts. And we will work with the participants to do that.

Okay. All right. So we do have a few minutes. And is there more questions, Seth, from online or that was it?

DR. CARMODY: There are more questions, but I want to make sure we engage the panel.

MR. PATEL: If they're questions to me just send them to the panel. Let's just do that.

DR. CARMODY: (Off mic).

MR. PATEL: Yeah, maybe. I'll just ask a couple questions. I said maybe. Yeah. So I know it was kind of difficult when we had an initial agenda to the site visits and then we then shifted really quickly to aligning very closely to understanding where things are. I know it was challenging for a lot of people who were like very regimented and sort of knowing what the agenda should look like. And by the time we were done we were like, yes, this is probably the right structure to short of have it. Do you want to share -- and I

actually don’t know the answer to this, so I want to see what your teams felt like after the site visit was done. And was it the right method to sort of engage people in the right way?

And I’m leading this question to this for you guys on the panel too. What would you tell the audience if they were to provide input to this program, what’s the best way to sort of do it? So can you sort of profess it with how your teams felt because you are on the front line, the teams felt differently. And then what would you tell the participants here in the public to engage with us? So I know it’s like a longwinded question. I’m going to start with you, Danelle, first.

MS. MILLER: Okay. Like I said, we were, I think, third on the list and it was, you know, in the same week. So we had prepared a lot of information in advance and had sent in our homework. That’s one thing we do really well at Roche is we do our homework. And when FDA came in it changed the dynamic. But I have to say it changed it in a really good way because we had a very flexible, open, very trusting relationship. But

let me tell you how we got there. They essentially blew up the agenda. Is we started out with a post-it exercise to get us all aligned on what we wanted to get out of the next day and a half. And I think that set the groundwork for really open exchange, trust, those sorts of things that I think are critical to true collaboration.

So I think by the time that FDA left we went, wow, this was great. But I think we also were like why did we do all that homework? But anyway, I know it's helpful.

MR. PATEL: I'm sorry.

MS. MILLER: I know it's helpful. So anyway, but thanks for such an open experience.

MR. PATEL: How about you, Diane? I think you had many people involved and --

MS. JOHNSON: We had many people involved. At J&J we are a very big ship. We don't always, course correct that quickly. We were one of the latter visits. So frankly the agenda had changed a number of times by the time the visit occurred.

And I think what we found so refreshing is the

team basically just shed the J&J slow ship. Because we had to be turning and we had to be turning very quickly. So the team really was very engaged and very excited by the iterative nature of -- and how we were able to come to the meeting in a very meaningful way because of the iterative nature. Because where we would have been was very different from where we were by the time you walked through the door.

MR. PATEL: So, Larry, I think you sort of embraced this whole thing about blowing up the agenda part, right, so after we started off with you. Having said that, how do you see, I mean, from an early perspective, how do you see this program supporting innovation? And then I'm going to turn it over to others on the panel to sort of answer the same question. How do you see this program actually helping innovation, but not changing the safety and effectiveness part or the confidence part?

MR. CARRIER: Yeah, I mean, we talked a bit about that. You know, that kind of safety is the anchor. I mean it's one of those things you -- it's just so inherently engrained to kind of think about it

in terms of KPIs and different things is, you know, it was a bit strange.

I think, I mean, one thing that innovation and really one thing, I mean, I was really excited about was we had a lot of people in the meeting who had not interacted with FDA before. And, you know, I could see, you know, there was, you know, it was really refreshing, I think, that, you know, we weren't under an audit, we weren't under an inspection and people relaxed. They tend to be pretty relaxed at Verily, but they were relaxed even more. You know, I think we're really able to engage.

So for me it was really getting the organization excited about the effort at all levels and all different kinds of discipline. So I think just from an organizational standpoint that will help us a lot, is really getting the broader organization involved in something. And again, involved in something that where, you know, we basically didn't have an agenda. We just kind of blew everything up and started from scratch. And then it was kind of like molding fog at times and then it started to really make

sense. And I think it was just good to get the engagement from the organization.

MR. PATEL: What about -- so let me just dive down one level deeper to the program itself. Like we had this vision about, you know, certify a company, build trust and understand and recognize trust in the company. And then based on the trust we'll figure out like whether they can send products straight to the market. And we would do a different kind of review if you had to review such products if it requires review. How do you think that sort of helps innovation? How does it help patients? So if, you know, if I can -- maybe I'll randomly stare at people. David, you're nodding at me, so maybe I'll just ask you. So how do you see that sort of helping, bringing products to market?

MR. ARMOR: Yeah. So I'll take the startup perspective for a second. Because so innovation is already hard enough, right. So within the context of a medical device company or biotech company there are so many factors that can go wrong that do go wrong and that obviously tanks certain companies. So I think the

more you can de-risk that process with standardization.

You know, one of the things I'm excited about precert frankly, and this might be a regulatory nerd in me, but it's really terminology. It's, you know, really aligning on a lexicon that we can all use to speak the same language. And I think that really drives innovation. Because if you can remove some of those uncertainties, especially in the regulatory process, which is traditionally, you know, unfortunately been the boogieman in a lot of discussions with investors and other organizations, you know, I think it allows other companies with fantastic products to get to market, versus failing earlier on in the process.

So I think that's really key exciting part for Pear to be part of the precert is to really try to help identify those issues that are common across startups and other organizations that really can compromise fantastic products otherwise. So --

MR. PATEL: So I'm going to jump to Jin and Jennifer too on the innovation. Everybody's doing innovative products here. So you come from a very

different perspective. And then I'm going to turn to Howard from a very patient centric view, like, how is it going to help patients? So if you guys can -- I mean, so we'll start with you Jennifer and say what would you think about will this model help innovation? So that's a question for you, Jennifer, you and then Jin.

MS. NEWBERGER: Yeah. So I think, I mean, one of the things, and we talked about this, we don't think of it as patients, we think of it as customers, as consumers, as the people who buy our products, right, that's our viewpoint. We have, you know, the most brilliant engineers in the world working on our products and we want them to be able to continue to do what they do and do it well without, you know, being haunted by the regulatory boogieman. I mean I think that's a really good way to put it. And so what we're hoping is that this program will allow that to continue.

I mean it goes to what Howard said, right, you want to build the products the way you know how to build the products. We know how to build a good

software product and we want to keep doing that. We don't want to have to change what we're doing. And so it's figuring out how we can use this program to allow our engineers to continue to innovate and to put great products out there. Not just for patients, but for consumers more broadly.

MR. PATEL: How would you answer that, Jin, from an innovation perspective?

MR. LEE: Yeah. So I think one of the key elements of digital health is the data and the large amount of data that we expect to obtain from consumer devices. And we see that the algorithms and the services will continuously evolve at a very rapid pace. And so unless there was a mechanism for a regulatory mechanisms that adapted to that, we would still be forced to do a very, you know, a release every six months or so.

What we want to do is as soon as the data comes in be able to adapt to it and kind of release it, publish it right away. And I think this paradigm really helps. The fact that we can rely more on the post-market real world data, gather the evidence that

way and validate the process. So I think in terms of the way digital health is moving where it's more data driven it really aligns well with the industry.

MR. PATEL: Yeah. So I'll turn to Howard and say what from a patient's perspective? And I'll go to Adam next and we'll talk about if we have questions lined up here. So, Howard, patient's perspective.

MR. LOOK: So one of my favorite parts of the conversation when we were engaged with the FDA team was what is your responsibility and what is your culture about engaging with your patients? So you've got products in the market, especially in a software world, you can get real time feedback on how people are using it. You can get real time data on how easy your product is to use and what bugs are occurring. We actually have this new wonderful system that every time a bug occurs we get an automatic alert and so we can log it.

And so part of coming up with a process for us would be how do we take advantage of all that information? We even talked about social media. Like in this day and age you should be engaged with all of

your users, all of your patients via social media. In or space, the diabetes space we know that there are device companies that actively avoid some of their most active user communities online because they don't have a process for processing and dealing with all that and they feel like they don't want to be responsible for it. And so we talked about part of your culture of excellence is the -- whoa, sorry. I got so excited. It's the opposite of that, is engage with your community, be in those communities, be where your users are and gather as much information as you can. And show how you're feeding it back into increasing the quality and safety and efficacy of your product. And so I love that the FDA is pushing organizations to think that way.

MR. PATEL: Yeah. We'll take a couple of questions and then we'll come back.

MR. ZACK: George Zack with Two Harbors. Wow, it's hot. So we've heard a lot about your individual experiences with the Agency in this particular experience. One of the goals, outcomes that Bakul mentioned this morning was collaborative communities as

I guess one of the objectives of this whole program. I'm curious, while we've heard about your individual experiences, how much of that collaborative community has been occurring between the nine organizations? Were there phone calls from week to week to say, hey, they Agency showed up and you don't need the DHF, don't worry about that? And obviously that would probably be very tactical in the initial assessment. But have you also started to collaborate on some of those shared themes, some of those quality principles and to what end? Thanks.

MR. PATEL: Who wants to take that?

MR. LOOK: This is the saddest part for me about this process, is I wish that we had been collaborating all together. And I think we all gave that feedback to the FDA. So we mostly were one-on-one conversations. We're actually all getting together on Thursday for the first time in person. But, yes, a suggestion for future pilot programs like this would give us all an opportunity to engage with each other more actively, proactively.

MR. PATEL: I had to activate all one at a

time because the bandwidth. But anyways, I think we are going to. I think that is actually one of the goals for the program. This is a community. And I would ask actually every one of them to expand their reach into their networks to sort of help us sort of get that as well. So I've seen that already happen. Howard's been very gracious in getting feedback from his community. And I know Danelle and Diane actually spend a lot of time, Larry and everybody actually spend a lot of time talking to each other about their experiences.

But one of the things that we are encouraging, and I'll put a plug in for people who are thinking about forming communities, is we want people to form communities. Don't wait for FDA to form communities for you. So organize and come to us with your community and we would love to hear from you. And we'd love to, I mean I believe I can speak for every one of the nine participants, they would love to hear from you as well. And how do you sort of build this together? How do you sort of make sure that the program actually is from the best what's been happening out there. So

great question, thank you. Go over here.

MR. EVANS: Yes, Lestrain (phonetic) Evans. That's a good question, thanks. Because I'm looking at the panel and forgive me, VPs and CEOs. So the question I've got is you keep talking about it's real enlightening in your team. What was the makeup of your team? What was the organization (inaudible), was it software developers, was it just VPs, was it CEOs --

MR. PATEL: Go, go.

MR. EVANS: -- quality, regulatory, legal? Who is this team that was (inaudible)?

MS. MILLER: Yeah, I'll tell you, we had a really cool team. I'll put it that way. We had a combination. We had folks from R&D, we had software developers, we had quality, we had regulatory, we had business people. We had, you know, a room full of folks who were incredibly interesting and that's our cyber security experts. So we were able to bring in people who added a lot of different perspectives. And particularly when we got into brainstorming mode that was incredibly helpful. So it wasn't just our quality regulatory folks, which is -- as a matter of fact, FDA

said “Don’t make it just your quality and regulatory folks. Bring in other folks.” And that’s exactly what we did. So we all learned from each other, which I think was really great.

MR. PELLEGRINI: Yeah. And I’ll say from our perspective it was absolutely cross-functional by design. So you do have regulatory product, you know, healthcare strategy. You know, even senior executives, CEOs stopped by and participated. I mean so really it was a complete cross-sectional view of the organization. And I think that was another part of the refreshing nature of the engagement is we all shared in a common agenda in that meeting. So I think that multi-perspective approach to this process I think is critical.

MR. LEE: We too had a very multi-disciplinary team. We had guys from software, cyber security, production, strategy, R&D. Both from the US team, as well as the Korea team. So it was quite a big effort for us.

MR. PATEL: Larry, you were about to say something.

MR. CARRIER: Yeah. We had a very, very cross-functional team as well. The one group we didn't have there, which I wish we did, and we tried to get for the next day was human resources. So when we started talking about culture, I mean a lot of us could that, but then it got kind of into the weeds on some, you know, intercompany, you know, HR related things. So, yeah, I mean when it comes to people, everyone talked about people today, human resources is pretty critical to all of us too.

MR. PATEL: So one of the things we did in the kickoff calls with each one of them, each panel participant was -- we wanted to be as close as possible to the real operations that sort of existed in the organization. And back to what I had said before is we want to keep that as minimal as -- the translation as minimal as possible to what needs to be recognized. So we want to get you seeing in the signal world you think about walking the process. We were actually trying to walk the organization so we can understand what's happening. So where we are building a program as close as possible to the natural state of the organization.

So that’s exactly what we intended and these guys did a phenomenal job bringing people.

So I don’t know who’s first, but you want to go, Seth?

DR. CARMODY: Sure. Bakul, what’s going on with the excellence model? Aubrush (ph?), you know, CMMI, there’s a bunch of them. Let’s just pick one.

MR. PATEL: So you’ll hear more about that in the panel five. But we could pick one and run with it. I think it’s the matter of finding the best of the world. That we want to align completely to the excellence principles that we have today, that we put up there. Those are the keys things that we care about in the organization that we want to see excellence in. How they achieve it is what the other models sort of bring to the table. It’s like how to recognize it, how to sort of identify those things. And that’s where we are trying to find, you know, best practices and leverage some of the learnings that has happened over time and well recognized across the world. So you need to stop asking questions to me and address the panel.

DR. CARMODY: I’ll address the panel. What’s

going on with current excellence models that you're using and how are you envisioning using them leveraging their concepts, the things that you like?

MR. PELLEGRINI: Yeah. I think the one thing -- and I don't know if folks picked this out when we saw all the models this morning side-by-side. If you noticed they're -- a lot of them have some common ingredients and some common DNA people. To your point I think that's an excellent observation having human resources as part of it, the cultural aspect. You know, just some of the discipline around process. And really in my mind it's looking at -- if you look across all of the -- what are the common elements of that DNA that you could put together into one model? I think that's -- I think you'll find that the end product is very similar.

So I'm not sure I would get caught up in a certain model as much as I would say the core fundamental elements of those models that actually make sense. Especially in digital health and in technology and in organizational excellence.

MR. PATEL: Yeah. Alex, I mean when we talked

I know we had the same conversation. Do you want to share? I mean you guys brought up your entire like organizational structure, how you dealt with sort of -- how you had up your organization. And then we looked into that. So I think that's something the audience would be very interested in hearing your thoughts on.

MR. BISAGNANO: Yeah. I think, you know, our perspective having, you know, a very strong software component of our business that we saw growing considerably in the industry, and that's why we really were interested in participating in the program, but also running the clinical reference lab under CLIA. So kind of very, very beholden to a set of criteria that already exists for quality and organizational measurement with respect to performance of that business. I think we kind of continually gravitated to, all right, what's some of the things that we're already doing that might apply and do they apply?

And I think one of the challenges with other models is in some cases they tend to be overly specific to a line of business. And I think a lot of times the conversation we had to keep reminding ourselves that we

do genetics, that's highly specific. But at the end of the day something that fits us doesn't fit every other company building software for a medical device. So I think, you know, it was interesting discussing the various, I guess, possible ways that we can apply --

MR. PATEL: Right.

MR. BISAGNANO: -- elements of, you know, different quality management systems. But I think, you know, the intent to build something this specific and nuance and something that's agile and that learns is so unique. And I think we'll benefit, you know, investment in the space as well. And I think that's something that, you know, I didn't touch on that last question. But I can tell you that, you know, our investors are probably more excited about the FDA not having been in an industry that typically interacts with them. So I think it's sort of creating a bit of, as a communication, kind of opening the lanes a bit, which is nice.

MR. PATEL: Great. We'll take your question.

MR. BERNSTEIN: Danny Bernstein, metaMe Health. So I guess it's a chicken and egg question.

Are you thinking of a team and a company getting approved first or is it part of the first product going through the process? And then I'm wondering how it worked with Pear Therapeutics. That's probably to Bakul and David.

MR. PATEL: I would hate to answer this one. I would rather have you guys answer it. What do you think?

MR. ARMOR: So I think to be clear, the answer is TDB, right. So, you know, I think certainly, and I think Bakul would support this, there's -- you know, we're right now researching the precert framework. So I think it would be probably a little bit too early or optimistic to say what the approach would be for precert. I think certainly for us, since we would fall on that tier of products that are going to be, you know, SAM D with clinical validated end points for certain labeled claims, we probably have some of the most work to do as some of the panel participants in that vein.

So I'd say we can't really answer right now where we're going to end up with the precert program.

I would assume that there's, you know, some thoughts about that. But maybe, Bakul, you want to handle a thought.

MR. PATEL: Yeah. I think directly answering the question, we are at a point, as I showed you in my slides, we are at a point we're looking at, you know, putting in diagnostic terms, we are trying to figure out what's the right diagnostics to understand excellence in an organization. That's the one piece of the puzzle. The second piece of the puzzle is like how do you take that and then what does that get you for a product going to market. I think that's the second phase.

So right now the next two days we are talking entirety about understanding what's excellent organization? What should those characteristics be for the excellent organizations. And you see the work that's been done so far is purely about trying to get to that identification of those excellent principles in an organization. How do you get there? What does it look like? How do you objectively measure, etcetera, is what we're trying to figure out? Yes.

BERNHARD KAPPE: Hello. Bernhard Kappe from Orthogonal. Could you guy talk a little bit more about post-market feedback, how you guys think about it. How thinking has evolved as a part of this interaction.

MR. PATEL: Who wants to take that? Diane?

MS. JOHNSON: Well, certainly as part of our participation in the pilot we had an essentially pseudo independent work strain that was looking at how can you incorporate the concepts around real world evidence that would support regulatory decision-making. And how that could be incorporated into an agile software development process.

We have a real opportunity here. We're used to passive surveillance where we're sitting around waiting for complaints to show up. We can design our software to be providing us active feedback where we can modify the software, we can incorporate behavioral modification to improve the patient outcomes. We have a real opportunity here and so we spent -- focused a lot on that in terms of not looking at it the way we traditionally think about post-market surveillance. Obviously you need to monitor, you need to understand

if problems are occurring. But we were more focused on how do we make our software better based on the information that's coming out of the software itself. So it makes the cycle extremely short.

MR. PATEL: Go with you next.

MR. MCGOUGH: Hi. Jim McGough, Edgewood Medical. I was curious how you're going to address the issue of operational excellence with early stage small companies and the definitions that might apply for operational excellence for them, vis-a-vi, larger fortune 1000 companies. As many of the great therapeutics of the future might be being thought of by three or four people listening around the world and they might be at a disadvantage. Did anything come from your conversations about that?

MR. PATEL: It's a fantastic question. I think that was the very first thing that we all aligned towards it has to be applied to both ends of the spectrum. So I will, rather than me saying it, I would like to see what you guys took away. You want to go there?

MR. LOOK: So this was a real hot button for

me because --

UNIDENTIFIED SPEAKER: The mic's not on.

MR. LOOK: Testing. There we go. This was a big issue for us. Like Tidepool is thirteen employees. Like I think some of these companies brought as many people to this meeting as our entire company is, right. And so we really want this process to scale. It's got to achieve the goals of showing that the organization is meeting the excellence principles. But it's also got to work for a tiny startup, right. If you're, you know, one person in a garage or three people just trying to get funded and you've got a great idea and you go look at this new process and these new regulations and go, ooh, there's no way, we failed, right. This has to work.

We even talked about, for example, the do it yourself community. There's some incredible innovation happening right now in the diabetes device space where do it yourself open source projects are building really wonderful, safe, effective products. They should be able to take this process and apply it to what they're doing. And it shouldn't be so big and onerous. And so

that’s actually what scares me about some of the other excellence principle methodologies is, you know, it’s a standard stock this thick that you actually have to pay for. And if that’s what we end up with that will be a failure. This has to work for the small entrepreneurial team that wants to do something innovative. And it has to keep working for the big company like Samsung or Apple or Fitbit or Roche as they continue to develop their products. And I think that’s a key point of this whole program.

MR. PELLEGRINI: Yeah, I would agree. And I would say I think that was a fantastic call out of I think the challenge for all of us during these workshops. We all, I think, probably talked a lot about KPI normalization. How do you actually normalize KPIs across large organizations, startups, etcetera, and build a dashboard? And I think that is going to be the challenge that we have. And I think this is the next step in trying to solve that challenge is engaging the ten participants and the rest of us all together into one forum and figure that out. Because I don’t think it’s an answer -- we don’t have a solve for it

yet. And I think that's the part of this journey that we're on.

MR. PATEL: Larry.

MR. CARRIER: Yeah. And further on something Adam said earlier too, there's a question about excellence models. And, yeah, apparently there's quite a few of those out there. I think it's good for us to look at those, but at the end of the day too I think it's the elements of those that matter, not the model. So you have to go look at a lot of different models from all over the world to, you know, see kind of what's good in them. And where it may end up is we just call it whatever this group kind of decides it should be called.

MR. PATEL: What would you have the public sort of inform us on that particular -- how can we crowd source to the same goal that we are actually trying to achieve? I mean would say unanimously there's a big consensus that we need to scale this for all sizes. And we started off saying that. There is going to be some nuances that we need to sort of figure out. But what would ask be to the people participating

in this workshop and watching us online, what would you ask them give us?

MR. CARRIER: Yeah. I mean you've given us some really good ways to communicate with FDA, websites and the docket and email. But I mean maybe by the end of tomorrow there could actually be some groups put together, you know, some actual teams that can actually work on things. And not end of day two and then everybody kind of go home and wait for the next public meeting. I mean that's not really going to work. So I think, yeah, it really is grassroots, so maybe that's something each moderator can kind of take on in their session, is just like how can we make this live, you know, beyond tomorrow?

MR. PATEL: Yeah. Yeah.

MR. SILKAITIS: Hello. My name is Ray Silkaitis from Amgen. And I think one of the things that I'm a little bit curious about for all the participants, after the FDA visit did you change your systems? How did you then respond to the visit and did you change the system in a more liberal way or more conservative way? And be a little more granular, you

know, did you get rid of the DHF?

MR. PATEL: Yeah. I --

MR. SILKAITIS: (Inaudible)

MR. PATEL: He needs to put a dollar in the jar, right.

MR. ARMOR: I want to take this one because I think, you know, the FDA visit was a blessing and a curse. So I'm going to take a contrarian view for a second and explain why. So, you know, a good anecdote of that is obviously we emerged from this meeting with folks that, again, have come from more consumer background, that haven't worked in regulated industry. And so we're not after this meeting, you know, in meetings and sessions and technical discussions. And, you know, you hear somebody say, "Well, but Bakul said we don't really have to do that." I'm like, "You know, we still got a 510-K next quarter, so let's relax with that for a second.

So I think that's actually a really, really good point. And how we're adapting past the meeting is really a little bit of both. I think we still have the current framework that guides us, right. I think

unfortunately we're not at a point now where the precert is done. We have a regimented, you know, process that's called precert that we know exactly how to go through. So we still have to kind of follow the process that we've been following in the past. But I think this engaging with FDA has really allowed us to think a little more creatively about how we map certain, you know, agile based SDLC processes back to 820/30, for instance. That's something that, you know, a lot of you probably struggle on a daily basis with, change control, right. So change control is something that I think, I don't know if anybody else on the panel talked about, but that's one of the biggest thorns in my side and as our sides as a company, right, and maybe industry wide. How do we take something that's so fast like software developments with these iterative life cycles and really control design changes? Which theoretically a lot of what we're doing is design changes. So those are things where we're trying to still meet the intents of the current regulations and standards. But we really want to approach it the Bakul said, which think about the science, think about the

basic technology and make decisions using that clinical risk based process. So, but, yeah, it was definitely a big topic after the meeting. So --

MR. PATEL: How about others? Jennifer?

MS. NEWBERGER: Yeah, I mean we didn't change our processes. I mean as I said earlier, I think, you know, part of what we're hoping to get from precert is exactly to not have to change our processes no matter what. We want to keep doing what we're doing and make good products. And to the extent, you know, we did not get rid of, you know, DHFs to the extent that we have them and, you know, I think the idea right now is just that, you know, we are going to proceed under the current regulatory pathway. I mean I think that the message that we got, I don't know if other sort of saw it different, but that that's what is supposed to happen right now. Is that you just proceed under what exists, you know, maybe keep Bakul in the loop more than he wants to and, you know, see what happens. But I think right now there is no precert program and so there's nothing to change a system to accommodate.

MR. LOOK: Yeah. Can I --

MR. PATEL: Yeah.

MR. LOOK: So we had already changed. We still have a design history file. It doesn't look like the one that the guidance document says it should probably look like. We use Trello and Google Docs as our design history file. And I think the most important point, both through this pilot program and just in general, my advice to all companies out there with very conservative old school regulatory group is every guidance document has this incredible gray box on the front that says this is just our current thinking on this. If you have a better or different way come talk to us. Go do that. You need to think of the FDA as a partner. They want to hear from you if you've got a better way to build your product.

So we did that early on. We said, hey, you know, that's kind of silly. We'd rather keep our design history file this way because that's how we think about building software. And we showed it to the great folks at CDRH and Bakul and lots of other folks and they're like, "Hey, that's awesome. We wish lots of companies would do it that way." We're like, yes.

And so engage with the FDA, they are your partner, they want to help you make your processes right for safe and effective products.

MR. ARMOR: I'm really sad that there's such hatred for DHFs, honestly. I don't, you know -- anybody else loved it.

MS. JOHNSON: So at Johnson and Johnson we are looking to modify our process to have it be more agile based and kind of do the crosswalk to 820, but (inaudible) the whole design history file approach.

MR. PATEL: We'll take the last question. We've got five minutes and we'll do a lightening round for the panel.

MS. MANSFIELD: Hi. I'm Elizabeth Mansfield, I work for Grail, it's actually (inaudible) development company. And my question is, maybe Danelle and Diane can answer this, digital health covers are a lot of the space, there are a lot of things we could include under that monitor. Well, my company uses Agyle development processes and, you know, has a DHF in process and all that kind of stuff. Will this change things for companies for which software is not the product, but is

part of the product? For example, in vitro diagnostic NGS that has a sequencing pipeline.

MS. MILLER: You know, as we look at this, this is a first step, right. It starts with SAM D, there's also SIM D, etcetera. We're also seeing as we watch FDA, we see some of this being translated into things like the Memorial Sloan Kettering, you know, the 23andMe where they use some semblance of a type of precertification. So I can't speak for the FDA, but you know, we hope that there's some aspect of this certainly that goes to the more innovative types of technologies out there.

MR. PATEL: So I think we are at the forum maybe one minute, two minutes more. There you go. If I can ask the panel to sort of do a twenty second blurb, keep it at twenty seconds because we are trying to get back on track. What is the one thing you want the audience to sort of hear as we started building this program? I think you guys had -- you shared your experiences with the site visit, but it's like let's move beyond. Like let's like make it happen. What is it that you want to tell the audience and the public

that as ten participant to help us build this? What is it? So we'll start with you.

MS. MILLER: They're serious. I think that's really what I want to pass along is that the Agency is serious about collaboration, about coming up with something that really works for software. So let's give them the best ideas we have.

MR. LOOK: This is a revolution. This is as close to a clean sheet of paper when it comes to regulatory processes we're ever going to see. Everyone in this room has an obligation to share the best ideas they have and everyone out there in the world should be sharing ideas on how to make this as good as it can be. Let's take advantage of it.

MR. LEE: Yeah. I think this is really an unprecedented opportunity for the digital health industry. And I think we all should participate in this process and provide buy in so that we can all move forward.

MS. JOHNSON: So I think I would encourage everybody to think big. Not only think about the innovation of the product itself, but think about how

these products can innovate how we do clinical studies. You add sensors, you add wearables. We could revolutionize other aspects of the regulatory life, including clinicals.

MR. CARRIER: Yeah, I would say nothing is sacred here. And this is an unprecedented, you know, event. And let’s get to work.

MR. BISAGNANO: I’d say that this is an excellent, you know, opportunity to build that world where, you know, constant iteration and getting things to patients faster that can be extremely helpful for their health is a reality. And I think this is a true open dialog that we’ve just been very happy to be a part of.

MR. PELLEGRINI: I would say don’t hold back. Don’t -- if you have a great question ask it. Ask it sooner rather than later because you could go through the next couple of days thinking, gosh, I should have asked that question a long time ago and I waited two days to figure out the answer. This is about really active dialog. And I think that would be a takeaway from the on sites was ask the questions day one, right

away so you actually go into this incredibly informed and actually provide the inputs that are needed for this historic initiative. And I really think that if you do that you will be pleased at the end of this journey.

MR. ARMOR: Basically what Adam said. He stole my statement. So, yeah, don't hold back. Don't hesitate to reach out directly to the Agency on this. Because I think we're actually , we're looking forward to seeing what other crazy amazing ideas there are out in industry that can help facilitate SAM D products and similar digital health products in the future. So --

MS. NEWBERGER: I think that we all have to be comfortable being uncomfortable for a while. I think that the end result here has the potential to be something awesome, but I think it has the potential to be messy and difficult along the way. And that's okay. And it's not a space that most of us probably want to be in, but it's part of the process.

MR. PATEL: Well, with that give a big hand to the panel.

(Applause)

MR. PATEL: We're going to take a fifteen minute break; is that correct? Ten. And then we'll come back.

(At 10:48 a.m., break in session.)

(At 11:01 a.m., session resumes.)

MR. PATEL: Ladies and gentlemen, we're going to start our second panel. Can I ask you guys to take your seats? We're going to start our panel. We're trying to get back on schedule. FDA's core team, can you please come on stage.

UNIDENTIFIED SPEAKER: Ladies and gentlemen please take your seats, the program is about to resume.

MR. PATEL: Thank you. Okay.

UNIDENTIFIED SPEAKER: Sorry. We have a lost item from Casey Lee Hanley. Casey Lee Hanley, if you want to go to the registration desk they have your lost item.

MR. PATEL: I don't know why they left a chair in between me so we all sit here. You guys can hang that. Welcome back, guys. So I hope that last session got your juices flowing. We got deeper into the program right away. I want to give you guys -- I mean

this panel was set up to share with you, so a different perspective.

So here is the core team at FDA helping build the program. And they have been instrumental in sort of, one, helping us get to this workshop, and two, looking at all the information we collected so far. And they also had different perspective when we started and now at a different point on how they see this program has evolved. They have been iterating and evolving along with me and I want you guys to sort of hear from their own thoughts what happened and what changed and how they saw the interactions between the pilot participants and them.

So we had a discussion on sort of figuring out what questions we would ask. And I'd come up with a few questions for folks. I'm going to ask Linda, John and Cisco to sort of talk about one or two things you saw that were unique for software development. So we're going to dive deeper into development now. And perhaps you guys can sort of help us highlight some of the things that you saw and heard during the site visits. So, Linda, do you want to go first?

MS. RICCI: Sure. So I think we had a nice cross section of different companies, different sizes and looking at software development from those different lenses. I think one of the real advantages in partnering with, you know, any stakeholder is that from an FDA perspective a lot of times, as you all are probably more well aware than most of us up here, we're looking at a snapshot of what your product development is, right. I mean you put together a bunch of documents, you send them into us. You have some strange face reading them, it has to digest everything that is going on in your company and with that product at one time.

Through these visits that we had we were able to take a look into what the process is and how that relates to perhaps some of the things that we were seeing in submissions at other times. And understanding and really able to connect the dots with, you know, how is the software developed? What are the key nuggets of information that are important through the development of the software and how do those are do those translate to what a regulator may need to

understand about your product in any kind of a regulatory paradigm. So just having the ability to get to that point I think was very informative for our team, particularly as we move through this process.

MR. PATEL: John, do you want to take -- what from your perspective? And you've been in the software business for a long time from a different perspective. How would you see or what did you see?

MR. MURRAY: Well, I saw a lot of behavior which -- oh, thank you.

MR. PATEL: Sure, my pleasure.

MR. MURRAY: I saw a lot of behavior which was tending towards agile, which I think is a really good thing. And one of the examples of that was that I saw that the design and implementation of documentation was done in support of the design and the design requirements. And that resulted in a bunch of really good things. One is that the staff really believed in those documents. They really understood how to use those documents and they were willing to use those documents. So that was a very, very, very good thing.

And I also found a lot of companies that were

deeply respectful for compliance and regulation and law, but they didn't allow compliance to drive the bus. What drove the bus was the patient, the design of the device, so things trickle down from there. That was their regular starting point. As opposed to driving the problem strictly from a compliance perspective or the documents says I have to do this, or whatever. So that was a really good thing to see. I wouldn't have been able to discover that unless I actually had these in discussion with people and we had -- we were all leaning into the table and talking about the same kind of thing.

The second major thing I saw was that they liked to use automation. And the FDA likes automation. Even though I know that a lot of people don't adapt that much because of what they perceive is a validation requirement. So I think moving towards more validation and reuse of testing and continuous testing and stuff like that were really good characteristics that other companies many have done, but you would never know that when you're doing a premarket review or an inspection because the conversation is different. So the main

thing about learning all this was the conversation was different. It was cooperative. It was engaging. It was leaning in towards the same point.

MR. PATEL: So we're going to shift gears a little bit from just software to open practices, which I think Linda and you did a good job. I'm going to turn to Martin and see when you from a post-market perspective and your perspective, period, what did you see sort of what is the uniqueness of the similar -- our similarities to the current?

DR. HO: It's an eye-opening experience. For me I got a brand new understanding of clinical responsibility in a sense that if we expand the horizon from patients to users and we look at both, we -- I can aware -- that means the service makes me aware of the benefits of allowing more agile deferment and rapid deferment or iterations in the software developers, how much benefit that we can unleash for both patients and users alike.

MR. PATEL: How about you, Marisa?

DR. CRUZ: Thanks. Yeah. I think we saw a variety of methodologies employed across the pilot

participants in terms of the types of techniques they were bringing to bear in designing and thinking about clinical responsibility. But I think we saw a lot of similarities as well in terms of a focus on user engagement, a focus on incorporation of user viewpoints in clinical design and in testing. I think we also saw a spirit of innovation that was focused on lowering barriers of entry for patients to be involved in clinical studies and data collection.

MR. PATEL: Adam, you live in the NexGen sequencing world and genomics world. How did you see the -- what do you see the similarities in? I know we talked about it earlier in the day. How did you see this?

DR. BERGER: So I'd agree with both Martin and Marisa. I think what we're seeing in the field in general is sort of a movement away from individuals as patients or subjects and more as partners in research development and clinical practice. And I think we saw that in all of the site visits at least I was able to attend. We're seeing a real focus on, you know, whether you say a customer or you say patient. A real

focus on delivering value to these users at the end of the day, especially when you're thinking about the clinical development piece of this you're seeing an integration of clinical information and clinical expertise throughout the entirety of the development process. And even if it's not, you know, found within the actual company or organization itself, there's a lot of reach out to the clinical community to make sure that there's a real engagement and understanding of in-depth knowledge that people were able to bring.

MR. PATEL: Kathy, and Esther, if you could highlight some -- I mean we talked about leadership and culture a lot when doing the site visits. What's the one thing that you took away? I mean, Kathy, with your experience in the industry and, Esther, from FDA's perspective can you compare and contrast from what you saw?

MR. BAHR: So, sorry, so I'll start. So, yes, I spent a lot of time in industry, so I'll just say from a humor point of view it was really funny to go in as the FDA and not be on the other side of the table when the FDA comes in. My experience with the FDA in

the past was during inspections and managing a warning letter, so not the greatest of experiences. So it was actually interesting to see how the private participants really evolved, even within a couple of hours to like, oh, my gosh, they're here, they're friendly, the want to collaborate with us. So that was a really good thing.

The other thing that I was totally jealous of with many of them was their use of automation and the tools that they have. In industry I came from one of those big ships, so the ship does move softly or slowly. In FDA automation it's a desire, it's a vision. It's not there yet. So totally jealous of the automation and just the way that the leadership and the culture was plugged into almost every activity. So it wasn't a push, it wasn't a pull, it was just part of the culture. So that was really exciting.

MS. BLEICHER: And so for me one thing that I found very impressive is the engagement of leadership and decision-making. So that leaders seem to really want to understand the ins and outs of what the staff were doing and thinking about all of the different

elements. Thinking about clinical responsibility, thinking about patients, thinking about just the, you know, the market success of the product.

Also, with respect to culture the communication, it seemed like, well, every company had a different process for communication. There was a culture of communication within a team. And when there were different kinds of expertise that were needed to solve a particular problem that there was a mechanism for gaining that expertise internally and then going externally as needed. But that there was a real culture of proactivity and making sure that the expertise was there and considered in order to move the ball forward.

MR. PATEL: Cisco, what did you notice? I mean you've been working on the Case for Quality for a while and looking at it from a different angle and working with industry. What did you see sort of different, unique or similarities that aligns to what you're thinking?

MR. VICENTY: So actually, the opportunity to actually go into some of these sites and have a

different engagement it actually opened up a different set of perspectives, right. First of all, from the standpoint of understanding that in the software development space all the practices are there, everything is done really well. The integration of the user from the very beginning, various test stages, the concept of really understanding your product as much as possible right from the beginning. It was integrated throughout everything that was done at some of these sites. And in order to do that quickly they evolved their systems, right. We talk a little bit about the innovation, but we're talking about culture, we're talking about how they manage the knowledge, right. How they manage the information that they saw, the visibility that people had across the board, transparency internally.

It was a very eye opening experience in terms of saying here's where we'd like to see things drive, right. This really does enable a lot of the flexibility, a lot of the speed that we would like to see, even within a robust medical device manufacturer. When we got away from the language of, you know, not to

use the dirty C word of compliance, but you know, when we moved away from that language and the companies were able to demonstrate and show here's what we're doing and what we think we do well, when you take that step back everything that they were doing was basically very compliant. It's just much better at it than I think what we've been traditionally accustomed to looking at.

So it was really a completely different dynamic, something that I think helps evolve. Some of the questions I've been asked earlier today where this applies to other devices that aren't just software, right. There is a path, there's a connection, there's an evolution. There's work that we're trying to do to move things in that direction. But this really did highlight what the potential is and how I think as an agency we need to take a little bit of different perspective of looking at things, right.

I think Dr. Shuren who's there mentioned that, you know, it's been forty years since we've been in the med device industry. I don't think a lot of the modifications are not valid anymore. What's out there isn't applicable. The quality principles have been

around even longer than that. It's just the evolution of the execution of them. And focusing on that organization piece of it has been very eye opening and I think an element that I think we've missed out on.

MR. PATEL: So perhaps we'll take one level deeper and just from sharing the experience of what we saw takeaway. Adam, you had sort of conveyed to me a few times about you saw -- you went to about five site visits with me and you saw sort of the pattern of how we engage and sort of transformation that happened for both the FDA staff and pilot participants. Can you share a few thoughts about that and then I'll open up for other as well.

DR. BERGER: Sure. So, you know, going on, you know, getting to go I should say on five of the visits actually was a good way to really get a sense of what each company is doing, how they do it and ways we need to think about being flexible and how we engage there. You know, one of my epiphany moments was actually sitting, and I won't specific which companies, but I was sitting in there and the conversation turned to confidence about products and, you know, really

spoke to me about the need that we are going to have at FDA to really provide education about what does this program mean? What does it mean if you come through this program, you get certified and then you put a product out onto the market, what does that mean to be a precertified product as opposed to our traditional pathways of like 510-K or PMA or Denovos, how is that, you know, going to be conveyed to the public? How are patients and clinicians going to have confidence in using those products and knowing that there is that safety and efficacy bar that was, you know, met through our program itself.

So, you know, we are going to need to sort of evolve in the way we do things, how we talk to the public. Some of the, you know, piece that David was referring to earlier about terminology, making sure that we all speak the same language. I think we all have to figure out how to do that. You know, in additional we're also going to have to engage in the same way internally to think about how we actually do our review processes and what that's going to mean.

So, you know, a lot of this is going to come

down to ways that we are thinking about our processes, how we're looking at processes outside. So I think there's a lot for us to learn. There's a lot for us to learn from you, the ten participants. You know, as we keep hearing it's, you know, it really is that important for us to hear from the public. So --

MR. PATEL: So you brought up the point about the not changing the bar and, Esther, can you speak to that part?

MS. BLEICHER: Yeah. So I think that one of the questions that we got from when we were at many of the sites visits was, you know, is FDA really changing the bar? Because we are talking about a paradigm shift. And the answer is, no, we are not trying to change the bar in the sense that we're not trying to create a framework where products that are less safe and less effective get out to patients. That's not the idea. The idea is we see safety and effectiveness is really the floor. And here will be rewarding excellence and providing incentives for excellence and driving towards excellence.

So it's not about getting stuff out there that

shouldn’t be out there and just letting the gates flood open. FDA still takes its role seriously as promoting the public health. And as part of that role encouraging innovation is key and encouraging the kind of innovation that you all do in this room is really important. So the goals of maintaining safety and effectiveness and promoting public health in my view and improving innovation are aligned. And we really want to create something that maintains that safety and effectiveness bar, while also it moves us in the right direction in other aspects.

MR. PATEL: Anybody else on the panel want to add to that?

MS. RICCI: I’ll always have something to add. So it’s important to know that, you know, we’re not changing the bar. But we see so many of these technologies that can really be beneficial to patients. We want to make sure that we have the right paradigm in place so that we can incentivize the creation of these new therapeutics, these new diagnostics so that they actually can get to the patients the fastest.

You know, FDA has a public health mission.

It’s a public health mission to patients, to consumers. So we want to partner with industry and with patients to make sure that those goals can be achieved. You know, we see a lot of the innovation and we see, you know, a lot of people working really hard to make a difference. And we want to partner with those companies and those manufacturers so that we can all take that journey together and that patients can be the ultimate beneficiary.

MS. BAHR: Bakul, I was going to add one more point to that. I think we also acknowledged that we’re not experts at everything at the FDA. And when Jeff, Bakul, you know, Howard before was talking about partnerships with the public and with you guys, you bring the expertise to the table. So that partnership is real because we’re not going to all have the same expertise that you have. And what we don’t want to do is say, okay, we know this, how innovation is good here, but we don’t know this and we’re going to have to go a little bit slower. So that’s really also what we’re trying to motivate here is that partnership to bring that expertise and help us understand.

MR. PATEL: Yeah.

DR. HO: Yes. I would like to add that one thing that really impressed me throughout my multiple site visits are the passion of user, excellent user experience. They really care about measuring the patient's feedback and how to use them and leverage them to improve their product. So I think in some sense I would say that we should harness that power and energy to move above and beyond safety and effectiveness. Because effectiveness hinge partly on patients or users compliance to the product. And if we have a device as being thrown into a drawer and then forget about it, it wouldn't help anyone. But they are very helpful and they are very passionate about keep engaging the patients to keep on using that.

So again, it's a very positive experience. And if the cough syrup can -- the taste of that can improve just like the other software, then I think the cough syrup would taste very good today. But they, unfortunately, if they taste the same as it was thirty years ago.

MR. PATEL: Martin has a way with words we

found. Very good though. I just want to remind people online and in the audience if you want to hear about the experience that the staff had at the site visits that will be great just to ask those questions. While Seth is getting up there, I'll throw a question at the panel. Maybe I'll start with Marisa first. From what value do you see this program offering to public health?

DR. CRUZ: I think this program really does have a lot of potential. My background is as a physician and I currently see patients. And I see a disconnect in our ability to meet patients where they are, right, to be able to bring healthcare not only diagnostic and treatment oriented healthcare, but also preventative care to patients in their homes, in their daily life. And there is a somewhat disjoint between the way that they experience their everyday symptoms or everyday care patterns and the, you know, once or twice a year that they visit a physician's office and get there, you know, annual checkup. And so I think this allows for preventative and meaningful healthcare to be delivered in a way that synchs in a much more aligned

fashion with the way that patients live their lives.

I think that the second aspect that I would mention would also just be from the perspective of care providers. That I think we have struggled at times to be -- to articulate what it is that FDA approval means. What encompasses FDA approval to the provider community, to hospitals, to healthcare organizations? And I think that this program has the potential to provide some of the reassurance that people are looking for from FDA and to be able to articulate what really goes into excellence from FDA's perspective and give people reassurance that what they're prescribing to patients is a safe and effective product that can meaningfully improve care.

MR. PATEL: Thanks, Marisa. Seth, do you want to read out the question?

DR. CARMODY: The question is around collaboration. So we have nine pilot participants.

MR. PATEL: Microphone.

DR. CARMODY: Yeah. Hello.

MR. PATEL: Is it on?

DR. CARMODY: Check, check.

MR. PATEL: There you go.

DR. CARMODY: All right. The question around collaboration. So we have pilot participants, right. We have this workshop, (inaudible) workshop participation. What is the mechanism of participation afterwards? How are you collaborating with folks that our outside of that scope? How are you collaborating with our fellow partners within FDA, like CDER? How are we collaborating with our federal regulatory bodies, like CMS? So these are really difficult questions, but I wanted to emphasize the theme of collaboration, how are we thinking about that as FDA?

MR. PATEL: I can start and then I'll have folks sort of answer and expand on it. I think our goal has been we have created -- we have been looking for mechanisms to sort of engage in provide input. So what I shared earlier, engaged in my presentation is about engagement. We have the current three ways of engagement is like ask questions, look at the information we put out and then engage with us on a docket. We are actively looking for other ways to sort of engage.

In fact, we just had a conversation with a clinician is how can that group be formed? How can a group be formed that can provide us what's not useful for us or not scalable for us to engage individually? So I am requesting folks to form groups and collectively provide us that input. We would be very happy to engage with those groups and sort of bring that input back to us. So that's one thing. Do you guys have any other observations or suggestions for folks? And we've been thinking about for a long time

DR. HO: Yes. I would like to say that perhaps another group that we can further collaborate with would be the patient groups. For our site visits we understand how the users experience being referred in the program development, programs development process. But one thing that perhaps that I will see in the next phase is to understand and to collaborate with the patient group a bit better so that not only the user experience, but also who the user when they may turn -- may become a patient. So therefore it would be nice to see a collaboration on that part.

MR. PATEL: Okay. Yeah, Esther.

MS. BLEICHER: So I wanted to just echo what Bakul said and make a request really. That, you know, we can't -- there's not bandwidth to meet with every single individual, company, individual association, individual group. But we do want to hear from you. And it's essential for the success of the program that we really do hear from all the stakeholders and everyone who will be, you know, a user of products that will make it through this program, the people who will be trying to put products through this program.

So we want to hear from you and encourage you to think about ways that you think would be effective in communicating with FDA knowing that we have a bandwidth issue. So like, for example, Bakul did a webinar before and we were thinking, well, if that's useful for you in terms of providing input and getting information from FDA we could do another one of those. There are all sorts of innovative ways that we might be able to get input too. And you all the innovators, right, so we have technology, we have computer, we have the internet. So help us think about better ways of engaging you so that we really can get the input we

need.

And the last fuddy-duddy piece of advice that I'll give is please do comment to the docket. Don't discount it because that is the formal way that we collect information and consider information. And we read those comments. It's not just a parking lot, so please provide your input to the docket.

MR. PATEL: Cisco, you had something?

MR. VICENTY: Yeah, just to comment on that. Because we, you know, a lot of the activities and lot of these pilots we kind of get the same questions about, you know, the additional federal collaboration, the CDER internally, you know. Someone mentioned beforehand, right, the enforcement leg, ORA. We talk about CMS. I think we've all acknowledged those are great, those are our partners, those are additional stakeholders. In some cases they're aware, we've some engagement going on. But I think part of the thing that would be great to keep perspective on today and for tomorrow for planning is we've got a scope of influence, right, it's where we are. The better we focus and show success there the easier it is to start

to expand to some of those other partners as we move forward. If we try to tackle it all at once I think we get into some of the analysis paralysis that always kind of hits us.

MR. PATEL: Great. We'll take a question.

DR. BLAKE: Sure. Kathleen Blake with the American Medical Association. And so I'm already thinking a few steps ahead and curious about the thinking within FDA and also with your pilot project collaborators about labeling. Because we've not yet talked about labeling. But any product that goes through or is precertified by FDA or a company that's precertified its products will have a label. And so what is the thinking about that process, what it will mean in this environment?

MR. PATEL: So can I just probably just ask the question in return, and this is what we did exactly at all site visits. We're not -- so we do know what we need today and what we have, some processes that talks about labeling in certain sense. In this case, in this area what we are asking for people to help us build is what should it be? What should the right labeling be

for a software that is a medical device that a practicing clinician can sort of recognize? And I think that's the requirements. So if you think about that as a product requirements, we are looking for that kind of input and thoughts and perspectives, from your perspective. So we would like to sort of hear from you and help us figure out what that should look like. Do you guys want to add to that?

DR. BERGER: I just want to add. So this gets back to the education point that I was making before. And the question is what is going to give you as a healthcare practitioner representing the AMA, what is going to give you confidence to use that product? So how can we actually streamline our labels so that you understand what it means to be a precertified product? And how is that going to be translated to the patient? I mean these are some of the questions we would love to have input from you and the rest of the community on.

DR. BLAKE: So I will get my chance on the panel starting at one o'clock. Because we're already thinking of ourselves as we need to see the evidence. You know, how does it work in language we can

understand? We also need to know at the end of it how is it continuing to work so that post-market surveillance piece becomes very, very important. I don't think we want alerts every five minutes that a company has updated a software product. But I think it will be, and we'll be happy to participate in that conversation, about how much information is both necessary and sufficient so that we're able to use it in our clinical practice. Thanks.

MR. PATEL: Thank you. We are at the five-minute mark and I just want to be respectful of timing and sort of get back on track. So we'll probably take two questions and then we'll end the panel the last question. So I don't know who was first, but --

MS. MANSFIELD: I'll start.

MR. PATEL: Yeah.

MS. MANSFIELD: Liz Mansfield from Grail again. I was wondering if you were surprised by anything at the visits that went on either positively or negatively? I doubt it was negative because you didn't pick the(inaudible) visit. But were there things that took you by surprise, things that you

really didn't know about when you walked in the door?

MR. PATEL: I'll look to see if folks on the table could talk about that.

MS. RICCI: So I think one of the things that really impressed me in the site visits that I went to is just the openness and the collaboration that the participants had with us. I mean they seemed to really embrace this. You know, everyone knows I'm a little bit jaded and cynical. And, okay, maybe a lot. So, you know, I expected there to be collaboration. But I was really impressed with the amount of openness that the companies were willing to share with us about their processes, about the challenges that they have. You know, not only -- I mean certainly from a regulatory point of view, that goes without saying. But also just in development, you know, what are their challenges and what do they see that could be improved on?

MR. PATEL: Anybody else?

MR. VICENTY: Yeah. So just to add a little bit to what Linda said. Something that was very eye opening for me that was a big takeaway, it's a little bit of self-reflection, right. I think that there was

an awareness of maybe certain behaviors or activities that were happening or driven. Not necessarily because they were providing the best outcome for either the patient or the business, but sometimes just because the perception was that's what FDA wanted. So, you know, a little bit of self-reflecting and going back and saying, you know, that's I don't think a drive that we were intending to really get to. So really trying to redefine how we can communicate, how do we drive things a little bit differently so that the work isn't put on just fulfilling things for FDA, the work needs to be where it really matters. And we've got to figure out how to get that communication to us in some, you know, valuable way that isn't going to be a burden. I saw a lot of internal tension sometimes between people doing the right things and then people saying, well, this is what FDA really wants.

MR. PATEL: So let's move on to the next question.

MR. KIRWAN: Hi. Michael Kirwan with Personal Connected Health Alliance. We do the continued design guidelines. And part of my question is really your

observations and the openness to use standards and certification programs that are out in the industry. So if you could answer any of that, that would be great.

MR. PATEL: So folks want to take that? Yeah.

DR. BERGER: Sure. You know, one of the things that, you know, we found is that a lot of these companies are already certifying or crediting to existing standards. And I think what we're trying to do with part of this program is leverage those existing practices so that you don't have to repeat those or necessarily supply all that same information to us to independently verify any of it.

So, you know, the concept is really about what can we take from your existing practices to leverage into a program like precertification? That'll, you know, obviously go with all the industry standards that people are accrediting to. You know, we heard folks are actually doing things with, you know, HIPAA, you know, and other certifications that they're getting. So if we can actually make use of those I think that will be a benefit for us and you as a community in

order to achieve this.

MR. PATEL: Yeah.

MS. BLEICHER: This is not in response to the question, but I know that we're wrapping up. And I just wanted to say one of things echoing what Adam had said and the last panel, that, you know, there are a lot of questions that I'm sure you have. And some of you are brave enough to come up to the mic and some of you might not have been. We're here all day, so come and ask us your questions, we're here tomorrow, so that we can really have a productive collaborative experience.

MR. PATEL: So if you didn't hear that these people are around, you can ask them questions as we engage with you. And this is the part of having this panel to, one, let you know who is working on these programs and you can have them provide perspectives and aspects. I do want to sort of take --

MS. RICCI: Can I respond really quickly about the standards thing?

MR. PATEL: Sure.

MS. RICCI: Real quick. Okay. So CDRH does

have a strong standards program already. And there is no reason why this type of a program can't leverage the same benefits that we have seen, you know, in other areas with that standards program. I think it is important to use standards because, without sounding stupid, they standardize things. So, you know, to the extent that standards exist or standards can be created for information sharing in this area, I think it's very vital and is definitely something that FDA has embraced in other areas. And I see no reason why we couldn't here.

MR. PATEL: I just want to take a minute. We don't want to leave the question. I know we had a lot of questions about from the industry and developer folks. But I think the top of our mind is also staff that who is reviewing and engaging in this process going forward. Maybe Linda, Cisco, maybe you go down the line, just twenty seconds, like what message are you giving both industry and staff about this program? What should they be hearing and should be looking out at how can they be helping?

MR. VICENTY: At least I know from our

standpoint it's the message that this is all about better information, better understanding of what's going on within a company. A better way to respond and react so that the company can focus their resources better and us as an agency, there are things that we do not need to be or want to be in the business reviewing, right. There's more value to having some of our people who've got a lot of experience actually helping to drive a bigger impacting needle than just reviewing things on a product to product basis. So it's all about getting smarter about our resources.

MS. RICCI: Yeah. It's when I talk to staff, particularly inside the Agency it is about making best use of our resources, being efficient with our time. We're not lowering the bar, we're just being more efficient with the resources that we have so that, you know, people that can easily exceed the bar we don't have to, you know, use the microscope on them. So that's, you know, making sure that our internal stakeholders understand that and can embrace that.

MR. PATEL: So keep your comments really short because we are really over time and we want to get back

on track. So, John, go.

MR. MURRAY: You may not know this, but most of CDH is a very conservative risk adverse bunch. So when they first heard about this program, I think going back a year ago, they got that frown on their face. But I think we've been very successful over the last year because of our tactical team and talking to lots of people. I think that they understand we're not creating an easy street, as some people may have thought in the beginning. That we really truly have the same goal, the same standards in mind. And I think when we explain them to them they go like, yeah, you're right, there's many, many, many different ways to get to the target without going through the 820 funnel, as I like to call it.

And so we're making progress. It's still a work in progress. And we learn new things every day and we communicate. We have a digital health hour like once a month we pick a topic and talk to them. So that's one of our communication things. So we are making success. We're not completely there yet. I think if we unveil more and more of this they'll start

to go like, oh, I get that. It's hard to see it until you see it, right? So --

MR. PATEL: Yeah, Martin.

MR. HO: Yes. To borrow Jeff Nogen (phonetic), which is be a smart regulator. And we have asked the industry to think what it should be. And I think I would ask our FDA colleagues to think the same and to pick battles and to focus on things that we can do the best and to have a better education or resources to continue to make it a collaboration effort.

DR. CRUZ: I would say that I think my impression of FDA review staff is that when they get to know an individual company through the process of reviewing an application or a submission, they get to really understand a dimension of that company and where they're really succeeding and where they're trying. And that this effort is meant to expand that relationship to a sector of organizations to say that we are going to celebrate excellence and that we are going to give people credit where credit is due. That a lot of people are trying to meet or actually exceed our bar and we want to recognize that across the sector

of industries.

MS. BLEICHER: So what I've heard from FDA staff is sort of echoing really what people have said, is that first the first concern is are you lowering the bar? And once people believe that we aren't then they get excited about it. And we have a lot of internal interest. John mentioned this tactical team, which is really an enormous group of people within CDRH who are excited and including review staff who are excited about helping build this program from the inside, just like you all are helping us build it from the outside.

DR. BERGER: So, you know, at this point in the stage most will get to say what they said and be done. But, you know, I just want to echo again, you know, what you've already heard from everyone else is, you know, people are interested in this program. They're excited by this program. It's not every day that we get to build a new, you know, pathway for regulation in-house. That just doesn't happen every day. And there is a lot of interest in it.

We do have tactical team meetings. We have a larger group and it's across the entirety of the

center. It's not just focused in one group. It's not just up here as you see on the list. You know, just based on where we're all at, we represent the entirety. Every office of the center is actually engaged in this. And we're engaged heavily, we are all heavily invested. You know, the reviewers are interested in how we're going to be doing this, how we're going to be making best use of their time and most effective use of our resources. You know, it's a real program that, you know, I think there's a lot of engagement on and people are interested in seeing it succeed. So I'll stop there.

MR. BAHR: Yeah, but I'll add the last one. So I honestly don't know how some of the FDA folks review files, because you can get files that are 10,000 pages long, 50,000, the variability is incredible. So I think the benefits that the industry is going to have with this program are also going to translate into the benefits for the staff. So I don't think by any means they should feel threatened, both internally and externally.

MR. PATEL: Great. So I will take a minute to

thank the panel. They have been really patient and tolerant with me with the site visits and helping us build the program. Thank you guys.

(Applause)

MR. PATEL: So I think our next session is about open public comments, right, Marisa? Marisa's going to moderate that. So people who had signed up and already been notified should start their comments now. If you could, yeah.

MS. CRUZ: All right. Thank you all. So I'd like to move as Bakul said to our public comment session. And so I'm going to first be calling on preregistered and confirmed speakers and then on preregistered speakers who are on our waiting list. Speakers have been asked to limit their comments to three to five minutes. And if we have time remaining after the preregistered speakers have given their comments we'll open it up to comments from the general audience. So have the first call Sylvia Trujillo from the AMA. Not seeing Sylvia, Kanchana Iyer from Nobel Biocare. Okay. David Eng and Nishith Khandwala from Stanford University.

MS. IYER: Sorry, I took a moment.

MS. CRUZ: Oh, no problem.

MS. IYER: Hi everyone. My name is Kanchana Iyer, I'm Regulatory Affairs Manager at Nobel Biocare in Mahwah, New Jersey. First of all I'd like to thank the FDA for giving me the opportunity to say a few words today. Next I'd like to thank the panelists this morning. It was a great experience listening to your feedback and your input on the program thus far.

So I represent an industry involved in the development of customized prosthetics. In such an industry it's critical to engage our stakeholders and obtain their feedback based on their real world experiences. Part of innovation in such an industry and making modifications to existing product is achieved through gaining the voice of the customer. So now when you throw in the software component comes additional challenges with maintaining hardware and software development timelines while meeting current regulatory requirements.

The tenants of the precertification program appreciates the needs of an industry that develops

customized products and strives to get new products to the stakeholders as quickly as possible. The precertification program is an opportunity for industry to maintain its high quality standards in terms of products and processes and raises the bar for improved sustainability.

I'd like to applaud the Agency for taking this crucial step and in reimagining its approach to regulating digital health medical devices to better align with the iterative nature of software development. This platform can certainly serve to further support the safety and effectiveness of products that can continue to be brought to the public in a timely manner. Thank you.

(Applause)

MS. CRUZ: Thank you very much.

MR. KHANDWALA: Hi. I'm Nishith Khandwala and I'm along with David Eng who is over there. We are working with the artificial intelligence in medicine and imaging at Stanford University. First we would like to thank the FDA for organizing this workshop and giving us an opportunity to speak here.

We would like to open a discussion about expanding the scope of the precert program. In its current form the precert program aims to certify technology that first looks at the software developer rather than the product. This means that the certified software developers will be trusted to approve their own products after a rigorous testing of their own work in the most expedited form.

But what if in addition to the software developers we also include third party validators where certified validators would be trusted to approve the work of others after performing their own rigorous evaluation of the other work. The reason why we want to bring this on is we see a lot of use for this in the domain of artificial intelligence algorithms for medicine. While testing in a clinical setting is extremely important and has been highlighted by the FDA in its new guidance draft.

If any of this sounds interesting and you would like to learn more about what we do, in the spirit of collaboration, please reach us at the workshop or email us at hello@bunkerhillhealth.com.

That's hello@bunkerhillhealth.com. Thank you.

(Applause)

MS. CRUZ: Thank you very much. Next we have George Savage from Proteus Digital Health.

MR. SAVAGE: Thank you for the opportunity to speak to you today. I'm George Savage, I'm Co-Founder and Chief Medical Officer of Proteus Digital Health. We're the inventors of the ingestible sensor, which is a medical device. But it's also the technology that's incorporated in Otsuka's Abilify MyCite, which is the first approved digital medicine.

First of all, I want to thank the FDA for the innovation being shown up here today around regulatory science. It's not easy to adapt processes that have been in place for a very long period of time and I really appreciate that. And in these brief remarks I'm going to take the advice of some people on panel one, which is that we should be bold, think big, ask questions, you know, and have a proposal. So I'm going to ask the FDA that as big as this is, this precertification program, that I think is just a little bit bigger than it is already.

And before I get to that just a little context. Software, consumer based software on an old mobile device really is the next way in healthcare. We all should be very excited to see our patients and other members of the community engaging as never before with their own health, leveraging personal data that comes from sensors, sensors that are built into their mobile device. Sensors from non-medical hardware, like activity trackers and things. And also traditional medical devices even now with sensors imbedded in drugs.

Back to big idea. Panel number two someone just mentioned a few minutes ago that it’s not often that you get to reengineer a regulatory pathway from scratch. And so as exciting as the precertification program and what CDRH is doing and in the spirit of the 21st Century Cures Act I would encourage FDA to involve the other centers of the Agency on this endeavor so that everyone is up to speed with the innovative work CDRH is doing in this area. What the industry needs is a uniform standard, one that is patient centric based on considerations of safety and effectiveness that run

across, not just medical devices, but a combination of products as well. We don't want to leave combo products behind. It is sort of a legacy style of thinking that states that the way software is regulated is determined by the center that has authority over some aspect of the product running the software.

And so I believe that, again, in keeping with Dr. Shuren's opening comment about the same functionality being treated the same without regard of the platform that the same data from the same sensor for the same purpose should be regulated in the same way. And this will require a little process collaboration from FDA, but I think it could really help.

Just in summary, I'm very encouraged by the progress. This is the most sort of innovative dramatic, flexible FDA that I've seen and I've been doing this for nearly thirty years now. And it's really terrific to see the flexible thinking of trying to adopt a pace of regulation to ensure we maintain safety and effectiveness to the rapid iterative development of software that is helping so many of our

patients. And I just want us to be certain that as we have higher speed and more iterative software design getting more quality products to our patients that we don’t leave combination products out of the equation. Thank you.

(Applause)

DS. CRUZ: The last confirmed speaker for this session is Bradley Thompson from Epstein, Becker and Green.

MR. GREEN: In the interest of time I’ll just put it in writing. Let everyone go to lunch.

(Applause)

MS. CRUZ: Thank you very much. Okay. So we are now going to break for lunch. Folks who have ordered box lunches can pick them outside in the lobby. And all are welcome to eat in the cafeteria seating area upstairs.

(At 12:01 p.m., recess for lunch break.)

(At 1:10 p.m., resume session.)

MS. CRUZ: Just before we begin I wanted to say that as we have had the chance to talk to many of you earlier in the morning and over the course of lunch

we've heard from people looking for an additional sense of what are some of the details of the program that we're envisioning. And we wanted to emphasize that the focus of this first day, the focus of the entire workshop over these two days is on precertification. That first step of this process towards building a precertification program that Bakul spoke about in his opening.

The focus of this first day of the workshop is to really hear from a variety of stakeholders, what are your perspectives on precertification? What would that mean to various constituencies, to various stakeholder groups? And so we're hearing from a number of different groups and different associations today looking to represent the variety and spectrum of opinions and perspectives that are out there. Again, Bakul mentioned that we're viewing this as the tenth pilot participant. And the nine pilot participants who we've already spoke to represent a certain sector of the digital health industry. But we recognize that there's lots of other groups and individuals who are passionate about the space and who care a lot about how

it’s developed. And so we want to hear from them as well.

The focus of tomorrow is really more on the nuts and bolts of what would precertification look like? How could we start to draw some tangible data elements into a model that FDA can make sense of and use to assess the excellence of an organization? And so we encourage you to read the background materials that were provided on our website to give you a sense of what the discussions and tomorrow’s breakout sessions will entail. And we encourage you to attend and be robust participants in those breakout discussions themselves.

With that we will segue to hear from stakeholders in the healthcare delivery systems, stakeholders in the digital health industry and representatives of excellence models utilized in other sectors over the course of this afternoon. We’re going to follow the same format as this morning with a question and answer session following each panel discussion and then a public comment period for preregistered speakers.

So to start us off please join me in welcoming Cara Tenenbaum, FDA Policy Advisor as our moderator for the third panel session.

(Applause)

MS. TENENBAUM: Thank you, Marisa. I think you all have our speakers, our panelist's bios. So in the interest of time I will not read those. But I think you know who all of them are. What I want to talk about is building this precert program. And we want it to be useful for you guys as providers, as payers, as patients. And so I want to find out what the imprimatur of the FDA means to you, what it could mean and what it should mean in the context of this program.

And so with that just kind of a foundational question of FDA clears and approves drugs and devices. Does that already mean anything to you in your roles? Kathleen, do you want to start?

DR. BLAKE: Sure. So first of all thank you for allowing me to be here and share comments. I want a level set in terms of probably ninety-five, if not ninety-nine percent of the physician and other

clinician community would probably just say, oh, FDA approved this. And not really understand what particular pathway something went through. Whether it went through a full PMA, a 510-K and we're not talking about introducing a precertification program.

So I think that the education of where the safety and effectiveness, the reliability of these new software programs as medical devices will be really, really important. It is also something where we will want to have there be, and the word was mentioned earlier, substantial education about what this new program means, how it fits in the ecosystem and an iterative process for not just learning how it works, but also being able to provide feedback.

MR. BROWN: I could add a little bit on top of that. So I totally agree with Kathleen. I'm Adam from diaTribe. I live with diabetes and represent and organization that's focused on diabetes, so I bring that digital health lens through diabetes.

But I'll say that a lot of -- most people don't know the difference between clearance and approval as something to start with. And so even there

we're talking about education. And mainstream media mixes up clearance and approval, so there's a huge educational gap just in terms of what goes into those two things. And then as Kathleen was saying now we're talking about adding precertification, which I do think could be a game changer for the field.

And we're seeing so much focus in diabetes and digital health, on digital health in diabetes because the trends are just terrifying. But when you talk about -- I'm just imagining like say I go to an app store and I see that a product is FDA precertified. To me that doesn't sound any different from FDA cleared or FDA approved. And so I think the biggest message I want to leave FDA with is when you go out with this in the public you have to think about the name differently. So imagine instead of FDA precertified, it's FDA certificate of excellence for software development. You need something aspirational and exciting and that people are going to get pumped about, both for companies to apply for and market and also that people are going to take really seriously. And I don't think FDA precertified meets the bar. So you

need to put a lot of thought into the branding and naming of it on the back end, once you go live with it. Because right now it just sounds the same as clearance or approval. Or it'll just appear in fine print at the bottom. And I think it could be much, much more.

DR. AUERBACH: So I speak with like two hats on at my institution. I'll try to do the same here where I sit in the Center for Digital Health Innovation and what we're trying to lower the bar for innovators to do new and exciting things with software. So having a precertification program will help us, or whatever we end up calling it, will help us guide them to develop their software in a way that's compliant.

The other part of my life is basically managing the digital formulary for UCSF Health. And when we're getting bombarded with requests from vendors and external companies that want to integrate their apps, devices, sensors, whatever, into clinical care at UCSF. And there's lots of downstream effects of those requests that we have to accommodate and having precert upfront will help at least give us a standard dataset they can come to us with and say we've done these five

things. We've at least done these security steps.

And, you know, later in this discussion I can talk about the other things we would have to subsequently do even with this program. But at least giving us that starting place would be super helpful.

MS. TENENBAUM: Naomi, from a -- we've talked about the precert program and what kind of exists nebulously and what else, but what doesn't exist yet. But what assurances would you need from a precert program to feel confident that the products precertified or the products made by companies that are precertified are really safe and effective? What does that need to mean to you?

DR. ARONSON: I'm going to scroll back just a moment --

MS. TENENBAUM: Yeah.

DR. ARONSON: -- to the prior conversation. And I just want to add not only is there not much understanding between the difference between a clearance and approval, but the difference between what goes on in CDRH with regard to devices, what goes on with regard to biologicals, what the processes are for

drugs and there are accelerated approvals, etcetera, etcetera. So if we're going to talk broadly what an FDA approval means, because it's got a variety of meanings, and there probably is not much general understanding. So I wanted to broaden that.

With respect to precertification, I heard a lot of enthusiasm here. And I have to say it's good to see people excited and it's good to see people talking to people from other perspectives and other disciplines and other organizations. So that's a very positive thing. And I do hear some thinking about the regulatory process and how it can be more responsive and focused.

But I really don't understand what precertification will actually mean. First of all, Adam, you used the example of this app or this product as precertified. But as I understand it it's not the product that is precertified. It is the firm that is precertified and then by derivation all of the products of that firm. From a payer's perspective an FDA approval, clearance or precertification is simply permission to enter the market legally. It's

regulatory permission to enter the market legally. And it actually doesn't speak to whether anybody wants to buy it, whether it's better than something else, whether it fits into a clinical pathway, whether it has value or adds value.

So primary concern from a payer's point of view, and I would like to suggest in this notion of collaborating with different stakeholders, I think the CDRH innovation group of the early payer engagement is just starting out. But it's absolutely on point and the right principle. So I would urge that companies in the digital health space as they're thinking about the opportunities of precertification also think about a, I don't want to say collaborative relationship with payers because that has kind of the wrong edge, but an engaged and friendly and informative relationship with payers. Because we really would like for you to understand early on the clinical evidence that is going to be required for a coverage decision. And it is not necessarily what the FDA requires to enter the market.

And what I'm finding particularly perplexing and concerning in the discussion of precertification is

I don’t understand how the precertification process fits into clinical evaluation, which further for the international report is also an element here. Particularly with high risk devices, class three. And I am waiting for information about how these work together. Because frankly what matters from a payer’s point of view is the clinical evidence. And the evidence that outcomes will be improved in one way or another, whether that’s by if only we were too we could cure everything, which we can’t. But sometimes we can spare somebody an unnecessary procedure, an unnecessary test. How will we be looking at the clinical results of the digital health devices? How will be know what the clinical impact is? What is the evidence that’s going to be generated? How will it be accessible? These are all the questions I am asking.

DR. BLAKE: So I’m just going to add a thought that came to mind as Naomi was speaking. But also thinking about this further I think all of us are aware that certainly in this country we’re increasingly moving into a value based healthcare system. And in that new healthcare system the focus is Naomi has

mentioned will increasingly be on value, but also on outcomes and clinical outcomes.

But the change in relationships is I think important to realize, which is that although in the past and to some extent currently there might be a perceived adversarial or challenging relationship at times between clinicians and payers. Increasingly as we enter into these new relationships payers and clinicians will be on the same side of the table. In fact, we've seen this with some large organizations that have insurance plans, but also have clinical delivery systems. So the kind of information that will be needed by payers and the kind that will be needed by the clinical people may increasingly look very, very similar.

DR. AUERBACH: I would echo the need for, and this sounds like where the collaborative communities are going to come in, but some focus on post-market surveillance of these devices and tools. I think the thing in the health system is, well, the value and relationship to what we've already invested and our HR has to be part of the collaborative community going

forward. Because we've spent hundreds of millions of dollars in our health system. So a key criteria for how we incorporate things into our health system is what does this do that we can't do ourselves and will it save us money while doing so?

Because these apps and devices almost never, to our experience so far, have saved us upkeep costs. But as the technology improves and precertification software comes in better tune that, again, that may be something that is value to the health system, but it's very different in the evaluation you have for patient outcomes. And increasingly physician and staff satisfaction in an era where clicks and alerts and those sort of things are really strong determinants of how long we keep our staff and how much turnover we have. I mean hiring and that sort of thing is another key issue to us.

MR. BROWN: Yeah. And then just to harken back to this point on clinical trials and clinical evidence. You know, I realize from a payer and a physician perspective it's critical. But I would just strongly caution the FDA to be very careful about

requiring a lot of clinical trials and evidence upfront. And that's because a lot of the companies that are going to drive innovation in these fields are small and can't do clinical trials. They don't have the funds to do clinical trials. And the clinical trials are slow and so they can't keep up with the pace of innovation. And I know this is something FDA care about with real raw evidence, but we do need that balance. And I think often times getting a company to market quickly allows them to get validation and then do a clinical trial once they've iterated the product enough. And it's fair that that may not be enough evidence premarket for payers, but on the other hand if that allows them to get to market quickly and then get validation and then go to payers, I think that's a great tradeoff.

MS. TENENBAUM: So then, Adam, let me ask you a question. What about a product that maybe is part of a company that has precertification, but the product itself may be doesn't have the clinical evidence to show that. But we know that the company has these principles of excellence and is driving towards that.

Is that something that you guys would want to share with your patient community, would want to educate providers about or is that something that you'd want to wait to see later where it really lands?

MR. BROWN: Yes, I think it definitely is. And I'll just bring a diabetes lens to it. There is often not acknowledgement of how insanely dangerous diabetes is. And so when a company comes and says, hey, we're going to make dosing insulin much safer. Insulin puts 200, over 200,000 people in the hospital every year. So we're going to give patients an app that can titrate their insulin for them. That is objectively safer than the crazy paper protocols that people are using now. But we also transfer liability from a person with diabetes using non-digital tools to a digital tool that a company is now responsible for.

And it may be that they come to market without a long clinical trial showing that it's safe. But on the other hand we should always acknowledge the baseline risk that people have right now with current non-digital, unconnected, poorly informed therapy. And so I think to your point even if they don't have

clinical evidence, but it seems clear that the product works as intended and is going to be at least as safe as the current level of care, but probably as much safer, then I think absolutely.

DR. ARONSON: May I ask how you know it's going to be as at least as safe as the current level of care if you have no evidence, you're going on the theory? Do you know what's in that algorithm? Do you know how it gets its positives and negatives and selects out and titrates it? I'm concerning about that black box.

MR. BROWN: Yeah, I think that's a fair point. And the way I would say it is what most people are doing is really dangerous right now. And so we can't ever be 100 percent sure about the risk of any product or software. But I think our bias should be to get things out faster and get -- collect evidence in a real world setting. And I think limited launches are fine and companies are doing more limited launches in digital health for this reason. But we shouldn't wait to collect clinical evidenced and clinical trials that

are published in journals. And we shouldn't let that stifle the field. I think that would be a huge failure for digital health.

And for the gap between what we can do with technology and what is on the market now is massive. It's embarrassing. And I think we should think really hard about what is driving that gap and try to close it as much as possible. And I think FDA is trying to do it with this program. And so my bias is to move fast, even if we don't have the clinical evaluation for you to make a payer decision.

DR. ARONSON: So may I just probe on this a little bit?

MS. TENENBAUM: Sure.

DR. ARONSON: Because I think there is an assumption here, an underlying assumption that somehow clinical evidence is onerous, clinical evidence stops innovation. We should have a bias to innovation. Maybe so, maybe not. But I believe that for certain questions you could get an assuring level of clinical evidence relatively quickly. I'm very worried about basically almost giving a pass on that by having a bias

or assumption that it must be better. I'm not arguing that what we have is not so good. But I think we created a great dichotomy and perhaps do ourselves a disservice by always assuming that it will be too long, too hard and will stifle innovation. Maybe that's one of the assumptions, along with other assumptions that we need to start rethinking.

MS. TENENBAUM: Go ahead, Kathleen.

DR. BLAKE: So I'm struck by the conversation at this point. Really particularly by the observation of someone with diabetes, which is that no -- you have a deep knowledge of the basic risk associated with your condition. But secondly then it is a risk that allows one to then say I am willing to accept the risk that might be associated with using and as yet we might say incompletely know product.

So if we try and work our way through that because certainly that's been done in the area of pharmaceuticals. Of people at higher risk they may enroll in clinical trials or they may get exceptions, they are allowed to use things. So I think that this enterprise depends on understanding basic level of risk

and acceptance of that. Americans are not perhaps as excepting of risk as we ought to be, at least in our health. Evaluation of risk tolerance in terms of a new therapy.

And then thirdly from the device standpoint having embedded within the software, and it was eluded to earlier this morning, embedded a learning system to then be able to rapidly iterate and have those learnings discriminated. So I will admit when I get the notice from my laptop telling me it's time to update this, that or the other thing I might not do it right away or I might say, you know, I just, oh, I forgot to plug it in tonight or what have you. But if I am somebody with a condition with a level of immediacy then I would need to know you get that update, you put it in so that you literally are operating with the best functioning software.

MS. TENENBAUM: So let me just -- I know you -- but I just want to jump back to, you know, that we're not, and I think the panel from FDA said this a couple of times, is we're really not trying to lower the bar here. But what we want to do is speed up the process,

right. And so we do want to ensure that products coming onto the market from precertified companies are safe and effective. And so I think what I hear you saying, Adam, is part of that calculation needs to also be risk in the patient population. What else needs to go into that? I mean I think I hear, Naomi, saying like don't ignore clinical evidence. What else needs to be part of that kind of body of evidence, and, Andy, I'm going to let you go first, to know that something coming out of a precert company is still safe and effective?

DR. ARONSON: Cara, may I clarify?

MS. TENENBAUM: Yeah.

DR. ARONSON: Because what I was responding to, and I think Kathy really clarified it very well, is that a patient can accept in certainty if they are told what the uncertainty is. If they are told that innovation and new is always going to be better than this risky, risky situation you have, then I think that's really not fully informed consent. So there -- I want to introduce this understanding of the uncertainty and elements of risk. And there will be

different levels of risk and certain acceptance. But I really do want to raise a flag about the assumption that something new is always better than what we have. What we have is something we don't know. Maybe if we're lucky we have equipoise and that's not so bad. But I do want to get that across, lest I be misunderstood.

DR. AUERBACH: So I was listening to Naomi. I had forgotten one of the points I was going to make. But I think implicit risk assessment I think gets to how comfortable we would be with a company coming in with a precertification is how you define risk. I think there was that slide earlier today that had that gradient that had like green on each end that was risk was not high or not low, or too low to be worried or too high. There's like places you need to really worry about that I think we'd have to think through as a community more. And once you precertify I think what I've enjoyed hearing about today is the communities that will result from that. And because the middle part is where we're going to have to commit to the evaluation.

You know, how we've squared this circle at UCSF is that we do a fair amount of pressing on that assumption that is this technology really going to be better than what we're doing already? Because we're constantly struck by how often unintended consequences end up being and should have been expected. So we have learned by the hard way of these things. And these are not only patient related ones, but things like data lost in transit or the service goes down when we need them or those sorts of things that are maybe local base problems for us now, but I suspect will be national over the long term.

But more importantly kind of taking the P&T model whereas we're going to do very careful formulary monitoring and assessment after we've put things into our health system. And we're early on this journey now, but I think it feels of a piece of where you're going nationally and I think it's the right way to go. Because, you know, sometimes you just have to fix and you have to try something new. And some things are polish around the edges. But if you're not committed to keeping an eye on the outcomes, and there's lots of

different axis we can go into, you're probably not doing the best you could by your patients.

DR. BLAKE: So talking constructively about what might be some of the elements or the features that would be extremely helpful to have. I think that we have to acknowledge that physicians in general are going to be more interested in the clinical information about their patients, the clinical conditions, the new therapeutics. They will be in most instances less interested in the guts, so to speak, of a software product.

And so where do they get the information that they need to choose one product over another? And where I'm going to with this is that we've been through a bad spell with electronic health record systems and with implementation of them. And we're in the recovery process I hope. But one of the features that was problematic and has now I think been reasonably well addressed was that there were gag clauses. And that organizations and individuals were not able to register their complaints. It was part of the contract that they had with the vendor from whom they purchased the

EHR.

So I would say go 180 degrees in the opposite direction, which is have the open forum. It was discussed briefly this morning. Have it where you actually interact with the users and you learn from the users and the users learn from you. So obviously I'm speaking to developers.

From the FDA standpoint I would say precertification then one of the criterion to consider is that there is a real functional bidirectional communication, frictionless as possible between the users and the developer. So that together we improve the products for the patients that we all want to see well or become well.

MR. BROWN: Yeah. Just to tie off the clinical evidence point, because I don't want to leave it hanging. I do think products will not be successful in the market unless they show clinical outcomes. I don't think it is FDA's job to assess whether a product will be successful in the marketplace. Meaning that clinical evidence can come after FDA approval or clearance, which would then inform payer coverage,

which would influence prescribing. But I think we have to tow that line carefully between requiring all that clinical evidence upfront versus on the back end.

On the point of other things besides clinical evidence and what I was saying. A test that I often apply to any new product that I try is what I call the no instruction manual test. Can I open up the product and figure out how to use it without reading an instruction manual? Because no one reads instruction manuals, no one reads 200-page user guides. That is the test for a product. If it is very usable you can figure it out just through the quick start guide, or whatever. And I'm thinking of apps.

The other thing that I think is super tricky is engagement. People talk about, okay, if you're spending time in the app you're engaged, it's a successful app. That is a very tricky metric. Because in diabetes the goal of any diabetes tool, app is to help people spend less time on their diabetes. So whereas Instagram or Facebook optimizes for more time in app, in diabetes the goal is the opposite. We want people spending less time on their diabetes, which is

actually a really tough thing to measure. And clinical outcomes is one measure of how successful an app is, but it's not the number of times that you open the app.

DR. AUERBACH: I just want to clarify one thing about my point earlier about -- so I think people get to these devices, these apps three different ways. They'll either find it on an app store themselves, patients. I think members will find them because there are herpetologists or diabetes special and they'll go to the app store and they select ones for their patients. Or because they want to use it in the context of clinical care day-to-day in Epic, whatever service they're using. They're going to go to their hospital and say you need to have this in my workflow day-to-day.

The first is going to be more along what Adam's describing. Can I use it? Is it useful? Does it seem to help me? The second one is kind of somewhere in the middle. Because I suspect we'll still want to see some measure like how is this really going to help me? I mean maybe I'll just hear that my patients like it, that's all fine.

I think from a health system standpoint we will probably want to see some, if not actual evidence, commitment to participating evidence generation. Because I think if we're going to apply this largely in the same as we do to drugs and devices anyway, because we have the same issues with stocking them in our EHR, keeping them up on EHR, maintaining our EHR that we'll need to figure out, you know, can we have seventeen diabetes apps in our system? Does it make sense?

So, you know, I think that, again, I bring up the communities again. I think I'm most interested in hearing where that goes because I think that is at least of objective commitment to that downstream post-market surveillance work.

MS. TENENBAUM: So when you at UCSF are making a decision about whether or not to put something in your electronic health record or the physicians work flow, would having something by a company that's part of the precert program mean anything to you? And how can we make sure that it is something that means something positive?

DR. AUERBACH: So every person we've talked to

in the last five years of working at CHI says they work with Epic. So I would not have that big a question on the precert program. But, you know, it's a tough question because I think every EMR is built differently than every other one. You see one Epic build, you've seen one Epic build is the rule we always say. But at least you have to at least have some understanding of how to build appropriate clinical physician support into an EMR if that's what they want to do. They have to at least have a process in place for assessing how it might impact physician, nurse, pharmacist workflow, increasingly pushing these into patient's personal health records.

I mean I'll speak Epics because in my charts like how is that going to affect someone's personal medical record experience at UCSF is something we think about a lot. And I don't think we're unique in this way. Like we like single source of truth as a principle for how we build data, our EMR, so that we -- if you are working in the app it's also the same data that your doctor sees and that your primary care doctor sees and the referring doctor sees. So those sorts of

things have to be part of the precert program. And, you know, they should be discussed at some point of the development, at least what is your policy around those sorts of things?

And there's lots of questions that we have. I think they were mentioned bleakly earlier this morning. But I mean security and privacy are only part of the question for us at UCSF. Like what is a company going to do with the patient's data once they leave UCSF? Because I mean it's maybe less relevant to someone who buys an app and says I agree to use your data use agreement, which no one reads either. But if you UCSF is going to contribute data to a patient's medical record and then send that data out to a company to get digested and algorithmized, you know, are those data are going to monetized for other reasons? Are those data secure? And those are the sorts of questions we ask a lot of companies, particularly the data analytic companies.

So those are kind of very specific examples of things we think through. And they're all very different from case to case. And the challenge I think

for precert is going to be creating something that is kind of useful enough across the breadth of things you're going to see, but also specific enough so that those of us who are thinking about these communities or want to onboard the things into EMRs could at least start the discussion at a very different place than we are now.

MS. TENENBAUM: What about the rest of you, what does precert need to have to make it something that is, you know, a gold star, that is a plus in in some way? Naomi.

DR. ARONSON: So this is really picking up from some of Kathy's points. I think transparency is extremely important. And that goes over several dimensions. One dimension of transparency is what are the criteria for precertification? Another is how did this particular organization meet those criteria?

The algorithms themselves we need to know something about the scope and the limits of the data that built the algorithms. I'm going to make up an example. And maybe it's silly, but the point is not. Suppose we have a software that will predict an MI

within 48 hours and do something to intervene. But all the data it's built on is from Caucasian males age 45 to 65. Is it generalizable? All right. So there needs to be a standard format of the scope and the domains so that we can be informed. We've had many experiences of non-generalizable data and it's a continuing problem as we think of diverse populations.

Finally, I think if an organization is an organization of excellence that it should have complete pride and transparency of maintaining a registry, of the outcomes of its products, a complete registry that captures all cases and that has public reporting probably on an annual basis. And some of the ideas I'm presenting here are actually in the peer report on registries for implantable devices. But some mechanism for bona fide researches to validate that data. Some mechanism for making it available in a peer reviewed format. And journal publication is not the only kind of peer review.

So those elements of transparency are critical. I don't know whether we should trust without verifying that an organization of excellence is

actually always and continuously without fail bringing us excellence or how it may be different from other organizations that don't happen to have that certification.

MR. BROWN: Yeah, just to add a little bit. I completely agree on the point about transparency. And I think, you know, I want to salute the Tidepool team who has been very transparent about their precert process. They've blogged about it, they've share all, you know, this post of 101 questions to ask if you're building great software. And then they actually shared that publicly and ranked, you know, scored themselves ranked on it. And so I think when this rolls out if an organization is precertified we should be able to see what are their KPIs? How do they rank themselves against the KPIs? When was it last updated?

And then things like, I mean, this is going to be a big change for FDA, but like a website that's more intuitive to navigate. And things, easy links, like FDA.gov/precert/scorecard. Like give us links that we can remember so we can look stuff up. Because, you know, the 510-K database and the PMA database I mean I

look at those and they're a little dated. But you can do better. And I think this is an awesome chance to just totally change the user experience of FDA databases and websites and give people something they can look up and see exactly what an organization met.

And I think that will -- if FDA can make that public companies will be proud that they're precertified and then it'll get -- it'll generate more excitement for it and more companies will meet the organization, the excellence principles. And it will just -- the rising tide will lift all boats. So I think actually the more public FDA can be about what the principles are and how a particular company scores against them the better, the more successful the program will be.

DR. BLAKE: So I would totally agree with that and, yes to an easier website to navigate. One thing that we've not talked about yet is a commitment to ongoing excellence. And so there is the notion that it's not just how you did in the past or how you're doing today, but it's really how well are you doing going forward and into the future? And so I think that

it will be important to know how performance evolves over time. I don't have any fixed ideas about how frequently one would renew one's precertification. I think that that's a question the collaborative will want to address. And I say that in particular because since software is a medical device is something that will be iterated upon and is not a fixed object it really is the excellence of the performance by the developers every day you might almost say. And I don't want to hear about it every day, believe me. But I do want to know that that level of excellence is being maintained and ideally exceeded over time.

MS. TENENBAUM: So I'm going to open the floor to questions from the audience and from online. Nobody online? So then I'm going to take another --

DR. ARONSON: May I make one (inaudible) --

MS. TENENBAUM: Yeah.

DR. ARONSON: -- before we close, please?

MS. TENENBAUM: We're not going to close yet.

DR. ARONSON: So before we close, so I want to continue the idea of transparency and ongoing excellence to the need to evaluate the precert program

itself. Whether on successes, is it really putting better product out faster, is there adherence in those organizations? Then I wanted to bring up something that is a concern and that is possible anticompetitive effects inadvertent. But if some companies become the medical software giants will it really have a cost increasing impact? And I think that economic aspect needs to be considered.

MS. TENENBAUM: Do you guys want to add anything else on that point? Andy, I think --

DR. AUERBACH: Yeah, I was just going to make a comment quickly about updates. I don't think it's completely relevant to the -- I think there are two points. One, it feels a little bit like the joint commission's old model, they come to your hospital every five years and you polish the floors and you put all the people's stuff away and people know where the fire drill. I mean you forget a week later. I think this is what the communities will help do. Because if people are updating their software and outcomes aren't improving we're going to have a lot of downstream questions about how excellent really is. So I think

that’s important for us to think through.

And I think the other thing that will happen as we build these communities, again, I’ll only reflect on my personal experience locally, is that as these apps update they almost certainly break things on our side. They break the APIs, they break how work flows in the electronic health record, they change how we approach our care. Or if we change formally on our side some of these apps have to change on their side as well. So there’s going to be this extremely tight symbiotic relationship as these get deeper and deeper. And I think, you know, having the communities and the updates really clearly on a roadmap for us going forward is going to be really important.

MS. TENENBAUM: With that we’ll go to this mic first.

AUDIENCE MEMBER: Yeah, (inaudible) and this is a great panel and a really good day. I think (inaudible) sort of (inaudible) the users, end users to get to the most important issues on the horizon. Adam spoke to (inaudible) patients who don’t have access to affordable or usable products to manage their

conditions. (Inaudible) said that when we have direct communications with patients, something that (inaudible) that feedback you can enable that. (Inaudible) product or the outcomes, hopefully it was the outcomes. Because it's the combination of those two principles that I think (inaudible) trust in the system or (inaudible) in determining what products, what devices are effective in the real world (inaudible).

So the general question is a lot of data is available that would allow us to (inaudible) effectiveness in the real world. (Inaudible) privacy and then how do you see that as a stumbling block in the future (inaudible) we all want to see? (Inaudible) data sources (inaudible) all of us gathered (inaudible) products and product use and (inaudible). I just wanted to hear your thoughts on that.

MS. TENENBAUM: Yeah, and Andy, you talked about that a little bit about monetizing folk's data and taking that. I mean we talked about security as a KPI, but you talked about it a little differently, not as cyber security, right?

DR. AUERBACH: I was thinking more about people taking patient's data and they both thrived in their care at UCSF. You know, specific examples was our own personal care and turn that into a way to discover new drugs and devices that they make money off of. And as long as everyone knows that's the game, that's fine. I don't think that's the question though.

I think the question is more along the line how would you define the clinical outcomes? Is that -- I think that's where you were going. And that's a tough question, I think, because every app targets a different disease. You know, if you look at the suite of things that were here today there's depression, there's opioids, there's diabetes management. So the outcomes you're going to need to manage each one of those projects over time to determine from a self-serving standpoint are they actually making care of my patients at UCSF better with this device, that's going to be -- they're all going to be very different. I think that's why these communities will have to probably end up creating some disease specificity or population specificity.

But I think it is a fundamental question because I think it, again, just coming from the standpoint of both a practicing physician and someone who manages REMR digital tools, you know, it comes down to are we making care better? And that's almost always outcome driven. So and without those it's going to be hard, again, for us locally that's a fundamental question.

MR. BROWN: Just one point on the privacy. I think most people skip over the privacy policies. I mean they're written in legalese, they're hundreds of pages. So maybe you think about like a company has to have a one -- like a five bullet point privacy policy, like summarizing the top line. Or it has to fit on a single app screen what the privacy policy is, because right now people don't read them. So can we get to something that's better than zero, even if it's only five bullet points? I mean at least that would give people information about where they're data is going and they can acknowledge if they accept it or don't.

MR. CODY: Hi, Joe Cody from the College of Cardiology. A question/point that I had is the -- with

the lack of clinical data going into the development of in the precertification process there are existing networks of experts from physician and patient organizations that can provide a certain degree of validity to either applications and other sorts of software as being developed. How does that process, either existing or new developed network of experts, other ways to actively engage in traditional organizations and patients from both the company side and also the FDA side, how is that planned on being incorporated into this structure? Because I do think that can provide a degree of assurance to payers, physicians and patients if their opinions and expertise is incorporated early on into the process before the precertification process is actually completed and that stamp is put on. Thanks.

MS. TENENBAUM: So I will just say that, you know, one of the KPIs is product quality, another one is clinical responsibility. And we're going to dive into some of that tomorrow. But, A, Joe, I'd like to hear later from the ACC what it thinks. But, you know, what do you guys think hearing that question?

DR. BLAKE: So I would say that it would be crazy on the part of a software developer to not engage those communities. And to the degree that they will be able to identify base on their size and the number of eyes, sets of eyes that they have looking at these different issues, they will be able to help identify what are the gaps, what are the niche cases, so to speak, that need to be considered. And also they will be a source of the, I would say, the latest clinically validated best practices. So that as I'm thinking clinical decision support, I'm thinking chemotherapy, all kinds of things, that you would be able to know that you could keep up at a very rapid pace if you engaged the clinical communities.

MR. BROWN: Yeah, I will just echo that and say companies will not be successful in digital health at really moving the needle unless they get payers to buy in and say, yes, we want to pay for that. And if they get providers to say, yes, I want to prescribe that. And so I think in part like market forces will help with that. But it should be something -- I think what's good is all the digital health companies, or a

lot of them in diabetes they have huge clinical advisory boards like right from the get go. And I think companies are understanding that if you want to move the needle you need that from the start.

DR. BLAKE: I might just add that this notion of having an advisory board that might be let's say ten people, twenty people, what have you, although a good starting point I think is not enough. And I think about the traditional medical devices in which they might have been evaluated in say 200 people. And then it is the full profile, shall we say, of the performance of the device only becomes apparent once it's been used in 200,000 people. And so I think having different sizes of groups, the smaller group gets you started and then the bigger group is what keeps you successful.

AUDIENCE MEMBER: Hi. Henry Manhncke of (inaudible) Science. We build (inaudible) programs. I really appreciate the discussion from the stakeholders. And one of the reasons I do is because I actually (inaudible) this conversation more confused than when I started. But I hope (inaudible). I feel like what I

heard from the stakeholders was that the precertification process didn’t necessarily have a whole lot of value in the absence of a (inaudible) clearance or approval. In a sense that (inaudible) may be excellent, but who knows if the product actually works or not? Is it the intention of the precertification process to replace those more traditional clearances and approvals, or is it the intention of the precertification process will enable the clearance or approval to go more smoothly if the company had already worked with FDA (inaudible)? (Inaudible) My company is rated excellent, but we never collected any clinical data that showed that work and I wouldn’t expect (inaudible).

(Laughter)

MR. PATEL: You’ll be standing here all day. I think this is going to be a really long panel. No. Since the latter is about efficiencies, like the very first thing is about efficiency. How can you get better? So I agree with everything that’s said on the panel. We are not like lowering or changing the bar on clinical validation or evaluation. In fact, we want

that to happen. We want that to be happening in an extremely small way. I mean there are a few things that were mentioned I just want to touch upon it and then we'll get to the line here.

We are envisioning a more continuous model of monitoring. We are envisioning a more continuous model of monitoring. We are envisioning leveraging post-market data in real world and getting access to it, having access to it. Not just as a community -- just as a community, but also as we look at it from a federal government perspective and maybe even from the research community. So just keep that in context.

Just a little bit more than what we didn't talk about all day and we didn't have time. And it took us like a whole day with the pilot participants to get there. So we could spend an entire day in a Q&A to do that. And I will be happy to engage separately with these communities as well, get those things out of the way. So great feedback so far. So, yeah, thank you.

MR. ARBITER: This is such a wonderful panel. Thank you all. My name is Brandon, I'm from Tidepool. Naomi and Adam, when you were talking earlier about

insulin titration algorithms, Naomi, you mentioned a few words that were really key. One you said was a black box, that black boxes make you nervous. And then later on you talked about transparency. My question for the panel is as the FDA thinks about this precert program, what role does transparency play in precertification? And Naomi or the whole panel, if an algorithm had transparency, if it was published and the data behind it was published does that in your mind in some way reduce the risk? You mentioned that black boxes make you nervous. Does a transparent white open box make you less nervous?

DR. ARONSON: I'm sure it would make me less nervous. You'd still need to know does it work for what it's supposed to do. And does doing that actually improve outcomes, and as Kathy pointed out, increasingly show value? So I'm not sure that the actual publication of the black -- of the algorithm itself can answer all those questions. But I think it would be a good thing. I do think that there will be some reluctance around this in terms of the proprietary nature. That's why I suggested standard domains and

formats so that we at least know the parameters of the box.

MR. BROWN: I agree.

DR. BLAKE: Yeah. I would go so far as to say I don't have time as a clinician to look at all the algorithms. I don't. And so what I do need to know is I need to know what does the software do, what is its intended purpose? And it goes through, we'll call it the black box, the algorithm, and then I just need to know how does it perform? But the proprietary algorithm in the middle and the lines of code is not where a clinician will want to spend their time.

AUDIENCE MEMBER: So can we envision a situation where precert (inaudible)?

MR. BROWN: Can you just repeat it? You cut off a little bit.

AUDIENCE MEMBER: Sure. In a condition or situation where (inaudible) and perhaps FDA can restrict marketing (inaudible).

MS. TENENBAUM: In the interest of time I don't think we should.

AUDIENCE MEMBER: Yeah. No, I'm just kidding.

DR. BLAKE: I would just say it gets to the questions of labeling. And really and that was part of the purpose of my asking the question earlier is to say how far does the labeling go and at what point in the life cycle of the device is the labeling -- can the labeling be expanded?

MS. TENENBAUM: So in the interest of time let's hear the questions from the rest of the audience. I don't think we're going to have to answer them. But maybe during the break we can connect.

MR. PATEL: And I'll say one more thing, we do have a frequently asked questions page we just updated, based on the feedback we've gotten. I would encourage you guys to look at that also. I think that's what we know how to send people to answer questions easily on the website. But having said that, I think we are collecting these questions, they're important questions. And I've been taking notes as well and we will update that. I think some of the questions you have heard before and we have answered them. We just in essence of time I think we should just probably move on. But I do want to hear what people have to say who

walked up to the mic. So if you can make it really quick that will be helpful.

MS. TENENBAUM: Go ahead and ask the question and we won't be able to answer today.

MR. BURCH: Okay. My name is John Burch and I'm with the MidAmerican Angel Investment Group in Kansas City. We hear pitches from software entrepreneurs all the time. And I can tell you that I really commend FDA for what they're doing here, let me just put it that way. But once you have made some progress here there is going to be a flood of software of all kinds, clinician facing and patient facing. It's going to be tremendous. But I do have a question that hasn't -- about a topic that hasn't been addressed at least so far here, data quality.

Software in a medical device typically is collecting its own data, at least the immediate data that that software operates on. But what we're really talking about in the future is software that collects data that is collected or that uses data that comes from some other source. Obviously not everyone thinks about the EHRs. And that data is really, really lousy,

really inconsistent and it's dangerous. There's no way, and I don't know whether you've seen the Jason report that recently came out on artificial intelligence basically saying that artificial intelligence is bursting at the seams to go, but it can't really do much until the data problem has been solved. Just a cascade of error is going to result if we try to do that.

So we can't keep kicking this problem of data quality down the road. I'll leave it at that. Well, no, here is the question. Patent registries are booming right now. There's growth in the patient registry market from somewhere around $300 million a year to over 2 billion that are projected in the next five years. They're popping up all over the place. And unfortunately what it means is we now have siloes of research information, just as much as we have siloes of practice information. And FDA is going to have -- but nonetheless can registry possibly be a solution to the data quality problem?

MS. TENENBAUM: Thank you. We'll take that question, please.

AUDIENCE MEMBER: (inaudible 00:57:45) General Health. This has been a fabulous panel and lots of (inaudible) discussion. And I think in the interest of discussing transparency, it seems to be a common theme, when we think about the precertification program as being a benchmark (inaudible) that ultimately adoption does require often times care reimbursements and so forth. I think that transparency from entities like technology (inaudible) within Blue Cross/Blue Shield and really thinking about what types of (inaudible) and applicable (inaudible) will require (inaudible) would be phenomenal. As for the downstream activity after a company goes through these (inaudible) absolutely right that we still have that level (inaudible). But I think it comes (inaudible) and have a level of transparency around (inaudible).

MS. TENENBAUM: Thank you.

MS. HOROJEFF: Hi there. Jen Horonjeff with Savvy Cooperative. We’re actually a patient co-op that helps companies connect directly with patients to get those patient insights. So I am so thankful to hear that conversation up here that people really feel the

need to connect with patients.

So my questions actually more about accessibility to digital health and how are we ensuring that people have access to these digital tools that we're talking about? I think that even with Apple's announcement last week about having their health records be accessible through their new health app that's great for people who own Apple products. And so even thinking about those from an Android standpoint and for those that don't have access to this technology at all, I just think about, you know, within the precert program is there any way that it's mandated that it can be accessible across platforms, that these things can be given to communities that don't have access to them. So that's just what I would encourage us to still think about those communities that currently aren't using these same tools.

MS. TENENBAUM: Thank you so much. Thank you to all of you. And please join me in thanking our panel.

(Applause)

MS. TENENBAUM: We're going to go straight

into our next panel. Cathy Bahr is coming up to do that.

MS. BAHR: If I'm sitting down either way, whatever's preference. All right. Actually a little bit different order, I think. Back sitting down again. So the panelists in alphabetical order, we're going to go in alphabetical order of the association. So Zach. And please introduce yourself really briefly.

MR. ROTHSTEIN Great. Thanks, Cathy. Asif, if you want to do my presentation I can try to do yours. Hi, I'm Zack Rothstein with ADVAMed. I manage the association's digital health and software activities and also lead our sector called ADVAMed Digital Health.

I'd just like to begin by thanking the FDA, the digital health team, Bakul, Jeff, the whole group at the Agency for the work that they've put in for organizing this workshop and, of course, the tremendous efforts that they've taken to execute the precert pilot. The medical technology industry very much looks forward to continuing to work with FDA to move from the

pilot phase of this precert program to a functional regulatory structure.

Early on in our discussions with FDA we recognized the many benefits both FDA and industry would experience by creating a precert program. For FDA these benefits include continuing its mission to protect and promote the public health and working towards its goal for novel technologies to be brought to the US market first. And, of course, the smart regulatory approach to digital health tools and technologies, such as the precert program, as the potential to reduce FDA's administrative burdens, meaning that the Agency's resources would be free to work on more critical matters.

The medical technology industry would benefit, of course, from a precert program too. By putting in place a regulatory system that is calibrated to address the needs of software developers firms will be able to better focus their efforts on ensuring their software is of the highest quality, safe and effective and serves the needs of patients. This in turn has the potential to foster tremendous innovation across the

healthcare ecosystem as more developers and companies gain comfort in creating digital health tools and products.

As we considered -- I think I was off by a slide. So let's see. This is where I want to be. As we considered these benefits we developed a set of priorities that we believe are important to ensure the precert program has maximum impact and fully achieves its intended outcome. The five priorities were submitted as part of AdvaMed's comments to FDA's digital health innovation action plan docket. And we believe if implemented these priorities will help FDA deploy an efficient risk based regulatory framework that streamlines a firm's obligations and the Agency's oversight responsibilities.

So first, we believe the precert program should apply broadly, meaning that all software should be eligible to take advantage of the program's benefits. This includes not only SAM D, but also software in a medical device or SIM D. And the program should be software and platform agnostic. It's also important that the criteria established to determine a

firm’s eligibility for the program be transparent and objectively evaluated.

Similarly firms that participate in the program must be treated equally. This means that program eligibility and certification criteria should allow both small and large firms and establish startups to have the same opportunities to participate. Of course, this also means that certification criteria must also apply equally to all types of firms. For example, a large established firm with existing KPIs and development practices should be held to the same eligibility criteria as a small firm that may have fewer internal software developmental KPIs. But simply the playing field for eligibility must be level.

Second, the program should right size the premarket process so it is better aligned with software development practices. Relying instead on both the safety risk of the particular technology and the firm’s demonstration of excellence, proven ability to develop quality products and its commitment to patient safety. For example, software technology is currently subject to the Agency’s 510-K review program should at a

minimum be provided an exception or streamline premarket review. And software technologies that currently require a PMA Should be offered a streamlined premarket process.

Third, the program should allow for software changes to be made in an efficient manner once products are on the market. One example the program can look to is FDA's guidance of post-market cyber security risk management, which in many cases permits a firm to issues patches and other fixes for cyber security reasons without prior notification to FDA. When a product change does require FDA review, such as a change to the product's intended use, the firm should be able to leverage participation in the program to initiate such changes in a timely and efficient manner.

Fourth, with respect to post-market reporting obligations, the program should provide an exemption from such requirements or a streamline mechanism to do so. At a minimum we believe program participation should allow the firm to utilize Section 227 of the 2007 Food and Drug Administration Amendments Act, FDAA, which permits malfunction reports to be submitted on a

quarterly and summary basis.

And lastly the firth principle, we believe participation in the program should be voluntary during its initial stages. That means firms who wish to continue relying on FDA's existing premarket program, such as the 510-K, program should be permitted to do so. Thank you for the opportunity and I look forward to the Q&A.

(Applause)

MS. BAHR: Thank you, Zach. Asif, it is your turn now.

DR. DHAR: Thank you. My name's Asif Dhar, I'm the Chief Health Informatics Officer from Deloitte Consulting. And what I'm here to do is to give you a bit of an overview of some of our experience with some of the concepts that you've heard today.

About eighteen months ago we hosted a convening session at a conference called Exponential Medicine. It was hosted in the San Diego area and involved about 700 participants where we reviewed some of the high level concepts that were presented today. We hosted at that conference a short working group

where we took some of the elements and had a bit of a design session around things like what precertification might look like. And actually what was even more important at the time what an RDK might be. And I'll explain. A regulatory development might be and who might be willing to contribute to it and what the principles might be.

A year later we did a bit of an update with 700 participants again. We asked for some feedback and surprisingly it was indeed quite a positive, enthusiastic, but quite participatory, which was an exciting piece of evidence. We also built a prototype of what we refer to as an online collaboration portal so we could prototype what the experience might be. And we gathered some feedback that I'll talk to you in just a moment.

In between those two sessions we hosted what we refer to as a greenhouse or convening session where about fifty individuals representing the ecosystem and medical device companies, software developers and manufacturers, medical professionals, patient advocates, academia regulators and folks from the

finance community came together and dealt a series of concepts. There were a number of them that came up in the session. A couple of the data points that I wanted to bring up today. Many of those will be summarized in a white paper that we will release to the public subsequent to this session. And we're looking for your feedback to that paper, which we might continue to update as time goes on.

The convening session brought a couple of ideas up. And the first one was that we analyze the tolerance of organizations to what sort of clinical evidence and clinical data organizations thought would need to be provided in what setting and a quick framework was produced. Meaning those situations in which there was more and more clinically severe or important scenarios in general the trending theme was that people believed there needed to be more evidence. That's not surprising. There was an unmasked principle as well that there was a difference between efficacy in a controlled setting and effectiveness in the real world setting that people seem to separate, which probably makes sense to most.

There was also this thought to level the playing field people needed to be able to have access to what worked and didn't in a language that made sense. So this concept of a regulatory development kit, meaning what do I do, when do I do it and can I be in an environment where it's explained to me in a language that I might understand? So if I don't have a huge amount of regulatory experience can I harness the crowd of experience, professionals in the space? This became even more important with things like data standards and software development practices were noted. Some of which have already become available with some of the things that we've seen today that are already readily available.

I'll get into this one final concept of an online integrated collaboration capacity with the discussion of real world evidence and real world data. There was a significant discussion on how real world data would be used, when it would be used, how it would be used, what types of data would need to be exchanged. And to simplify a fairly complicated discussion this ended up being an incredibly important topic that the

regulatory science of which needed to still be figured out and against the sliding scale that I just talked about.

The final piece of the sliding scale was that there seemed to also be a sliding scale in terms of when normal clinical business process would be averted, either intentionally or non-intentionally. So you can imagine two axis that would well define a scenario with increasing amount of evidentiary standards that would be required in those circumstances. Of course, we didn’t have a statistical sample that was -- we didn’t have a sample that was statistically relevant. But we had general, you know, trends that I think were informative.

The higher the degree of clinical judgment being moved aside and the more severe a situation, you add those two together and in general folks thought there needed to be significantly more clinical evidence. We also assessed the impact words, a precheck sort of environment where data would be exchanged and we created this sort of friction score where there could be collaborative activities. And in

general the level of evidence slightly decreased in each of those settings, in each of those scoring. So anyway, the white paper will be available for your review, like I said, after the session.

Finally, we created a prototype. We put an online environment together with the model of what would it look like if we took the concept of Turbo Tax and had the exchange both in precert and in submission exist in that way. And we found that the RDK had a hidden benefit. Meaning if you're using a Turbo Tax type of environment you can hover, reveal in certain areas of your application process. And not only did it create a compliance function, it created an important educational one. So that was a fact that we didn't expect.

Some of the things that we have heard as well from the market in terms of things we need to pay attention to is, you know, why focus on software as a medical device? At what point will you focus on software in a medical device? It was just our feeling, in terms of the white paper, that knocking down the first domino from a regulatory science perspective was

an important area of focus.

We looked at the challenges of real world data and real world evidence. That was something that was brought up a fair amount. And then the feedback for our prototype in general people felt a collaborative environment would make it a lot easier for a new entrance to come into the space. Integration with the regulatory development kit seemed to be an incredibly powerful tool to allow companies without much experience to get in as it were. And then finally and incredibly important, a delineation of actually how real world data would be handled, when and how.

So that's a bit of our experience. We encourage everybody in this crowd, everybody that's listening to the conference and this wonderful discussion to try to do the same. You know, we're one experiment of many. And we learned a lot. I think the participants in our workshops learned a lot. But I think if we don't keep doing these sort of experiments it's going to slow down the development of what should be a collaborative process. So thank you.

(Applause)

MS. BAHR: Anand. Or not.

MR. IYER: I'm there.

MS. BAHR: Okay. Hi everybody. Anand Iyer, Chief Strategy Officer at WellDoc. I'm wearing a different hat today. Some of you know WellDoc, a digital therapeutics company in the realm of diabetes management. But today I'm wearing the hat of an officer of a newly formed organization, the Digital Therapeutics Alliance. And I'm going to tell you in 90 seconds what that is and then I'm going to jump into actually some detail.

We've taken a little bit of liberty, poetic justice if you would, in maybe giving a sneak preview of some of the things we might be doing collectively tomorrow in sense of a scorecard. How do we bring all of this thinking together in a manner that's measurable, sustainable, replicable, etcetera, etcetera, right?

So the concept of digital therapeutics, subset if you will of digital health, that's held I think to a certain set of standards. That amongst those standards include things like the ability to demonstrate

significant outcomes published in the rigor of randomized control studies, right. The ability to have a proper security architecture that's certified, if you would, by all the right encryption, authentication, etcetera, standards. Those that actually deliver a clinical and economic value, right. And very importantly as we heard from our friends at the AMA and BCBS Association, those that are integratable in the clinical workflow. At the end of the day if these things create a parallel universe we create a nightmare for ourselves. These have to be integratable into the delivery of healthcare as we know it today. And that's kind of where we're headed in the future.

We're super proud to be alongside a number of other companies in the alliance. And you see these names of people who are in many ways pioneers, early movers and shakers in the spaces across a number of different clinical domains. And when you look at the evaluation criteria, you look at best practices, you look at integration of the healthcare system, some of these things, one of the things that kind of jumped out at us is literally we formed late last year was how can

we bring together, at least with an equal six and rapidly growing, but how could we bring together the perspectives of these companies in terms of what we do in the realm of SAM D and how we think this whole FDA precertification process can actually move forward.

So I think I'm going to take the prize, if there is such a prize for the most wordy slide. But what I'd like to do, and this is it, what I'd like to do is spend a couple of minutes on this slide and kind of walk you through why we put this together the way we put it together. So if you squint really hard you'll see kind of in the background a Parthenon like structure. And in many ways we think that there is an architecture, if you would, for the whole precertification program. And like any other good architecture it has, you know, a series of pillars that are the foundational elements. It has a strategic vision, the roof. It has a bunch of enablers that are the steps at the bottom. And so in many ways as we started to dialog, as we started to be part of the workshops that Bakul and Cathy and the team organized we said, okay, you start with the top. That's the

mission and vision of the precertification process.

And it's all the things that everybody's already talked about, right. How do you in mathematical terms, how do you optimize innovation, cycle time, efficiency, business value, subject to the constraint of patient safety, efficacy, etcetera, right? So you're not going to give up on that, but you want to accelerate all the other things around that. So we said that's fine. But as we started to think through the pillars, you can see the pillars here and these are the same pillars that Bakul had in his presentation this morning. And we said underneath each pillar we ought to think through three layers. We ought to think through a layer of KPIs. So what metrics actually should we measure in each -- under each pillar, under each domain of excellence? And for each KPI we ought to go the extra mile. We ought to measure, as any individual company who wants to be a part of the precert process, we ought to measure where we are. So what's our current value? So we talked about transparency. Being able to put that value out there.

But we also ought to be able to talk about what a target is. And that's a really good exercise for us collectively. What are the right targets for what metric? And this is a market driven initiative, so let's think like that a market. What are the average values for any metric and what's industry, best in class, top quintile if you want to define it that way? Why is that important? It's important because it creates a basis of continuous improvement for all of us. If we see the bar for continuous improvement against a moving best in class that works in your advantage, right. You're just going to get better and better and better over time. Then we have an opportunity to push this forward.

So the structure of those tables, whether it's patient safety and it's measuring adverse events per quarter or it's measuring the number of severity, what issues in any given release, whether if you look at product quality and it's the number of bugs in, you know, every thousand lines of code, or if you go towards the right and you look at cyber responsibility, the number of crashes per incident, or the number of

customers that are affected, if you would, or subscribers that are affected by an outage, you can see a layer of these metrics. And then underneath the layer of metrics you have what, you have a series of best practices.

And the fun here is that not every company is going to employ the same best practices. A large company may have things that are already in place based on large standards. And in this case there's a difference between what and how. I think the precertification program should go after what? A set of requirements that says are you fulfilling this, this, this and this? We don't care how you do it. In fact, we want to know if there's more creative ways to do it that you may be engaging in. So we're not asking you to comply and force yourself into a standard. But if there are creative ways that work for company A and there are other methods that work for company B, so be it. But make no mistake about it you better hit those metrics because that's not negotiable. That performance level is not negotiable, right. So that's kind of the bar and we're not going to lower that bar,

right.

And then, of course, you have the tools. Again, not every tool is going to be right for every company. And then you have stuff that we'll actually hear about I think later this afternoon from other people and other quality organizations. Many people call it the motherhood and apple pie. I call it the fabric. It's the fabric of excellence, which are the things that you hear. How do you do agile decision-making in your business decisions, in your strategy? How do you do all of the focus on value, customers, partners and all the way up to society and sustainability? That's really important.

So it goes to the earlier point that says we have an opportunity to not just think myopically, dare I say, about the precert process. The precert process is mission and it's a journey in and of itself that doesn't just transform the opportunity for in this case SAM D, but in many ways what we can do and the value we can unlock for patients, for providers, for payers and our health economic system at large. So thank you.

(Applause)

MS. BAHR: Thank you. Anna.

MS. LIBMAN: So as we've all seen today the FDA team here and Bakul and Cathy and the rest of the team have put tremendous effort in creating this first product of the SAMD regulatory paradigm into the precert. And early on from the very beginning back in the summer we've heard the team saying over and over how important it is that this is going to be all inclusive for the small companies and for the large companies.

Small companies have limited resources. But when they really succeed they create the most impressive innovations that we've seen out there for our patient care. At Experian Group we work with companies that are small startups from all over the world. And in the last couple of weeks or couple of months now we've been working with Cathy and the team to help to try and save some of those thoughts three of our companies that we've included within this exercise have done. And so we've sat with three companies that are three small startups and we've developed scorecards with them and identified KPIs that I'm going to share

with you today.

So the companies that we included here, just to give you a quick example of the sample that we have, all have (inaudible), they're all class two devices. And all have developed a quality management system over time that are really good. And then the other thing I want to mention is that the companies that we've included here have provided a pretty diverse insight. One, because they are at different stages of commercialization. Two, because they use different types of technologies. And three, we learned that it's really important to account for the different types of customers they use and the users that the company has because they do (inaudible) that you'll be able to use.

So today I'll share with you, I'll take the next couple of minutes to talk about some of the learnings and the takeaways that we've had by creating these scorecards with those companies. Two, some of the concerns that we've heard. And then lastly some of the APOs that we started seeing and generating to make this an all-inclusive precertification program.

So some of our takeaways, first of all, I want

to echo the first panel today from the pilot participating companies. All three of the companies that we worked with also said that the (inaudible) principles really do cover the areas that they are most concerned with. And so through our exercise, just to put changeable things, we even called them essential principles. And so those five principles really speak with them.

But we did learn that in the different stages of development of the company and the product, before market and after it's out there and it's being used, companies tend to focus on different essential principles. And then they over time develop really effective KPIs for all five essential principles, if you will.

So upfront when companies are figuring out their product market fit they're really focused on the patient safety element and they're really focused on the product quality. And so we've seen that it was really easy for companies to identify KPIs that they work with day-to-day for those area. But in areas like cyber security they were having a little bit more of a

hard time to define that. Not all companies. So this is where the product, who you're selling the product to, who your customer type is and the type of user that you have really played into effect. Because when companies sell directly, for instance, to patients, if you have a mobile app that you can monitor and you're hosting data on, for instance, AWS, it's easy for you to see what the cyber security infrastructure is going to be because you're relying on these hosting companies.

In other situations when a company is selling to healthcare systems and clinicians are their users we saw that they feel like that before you actually have those contracts with hospitals and you have a product that you can sell some of this like cyber security KPIs are pretty hypothetical, if you will. So we've seen a lot that we have a lot of those leading indicators that come into effect and not so much the lagging that we see more so after the product is in commercial use.

The other thing I want to mention here is that not just the business model as to who you're selling it to, but also the sales model of the company played into

effect here too. So when companies that we were talking to were considering direct sales, so if they have the exposure to the customer, versus other companies that wanted to do the licensing model, you create a product and then you sell it have to be incorporated within a larger product, maybe a GE or some other company, they have different accessibility to the end users and to the customers, meaning that they're going to have different types of KPIs.

So if right in our current environment both companies and both models would have had to create some kind of quality management system element of it and then get their 510-K clearances. If we're doing the precertification program now we have to think about, well, companies that have limited access to their end users will be at a disadvantage at some point.

Then lastly I just want to mention here that because companies are tight on resources you want to make sure that -- through our experience so far we learned that, you know, there was a lot of questions. Okay. What's the scope of this essential principle? What's the scope of the CDPs? The principles are a lot

easier than the CDPs to figure out how to work with. And we've heard that they might be changing or it looks like there will be a different structure. But as we're building or as FDA is developing guidance documents and you're developing resources and programs for companies through this transition in the next twelve months or so it's really important that we have really solid examples and definitions so these companies can come up to speed really quickly.

It is a potential kind of concerns that we've heard from companies where around, okay, if I'm a particular model or if I don't have that many lagging indicators upfront because I've never had any product out there, am I still going to be able to score as high as other companies? Because I am following excellent development processes for my software development. I do have the best in practice people that want to make the best patient care. And we know how to make medical technology. So will we be at a disadvantage if for some reason we tend to have more of the leading indicators that are qualitative than those quantitative measurable, actionable indicators that will come later?

The other thing is that, as I mentioned earlier, sometimes through this exercise when we asked companies to identify KPIs they were like, okay, let's put everything that we can possibly think of under these criteria. And then they went back and as they iterated they started removing things that they realized that it's not really a useful measurement that we would actually go about using. And so as we're building these scorecards it's important to consider to not encourage companies to just dump whatever KPI they find in the library, but actually select those that are super (inaudible) and that they can track over time.

Lastly I want to mention a couple of ideas that we started playing around with. We've heard over time, or through multiple panels today, that we want to make sure that this process allows for flexibility. And there's some evolution of the scorecard and the percent program. As one of the participating companies said that, you know, you don't really know how things are going to play out before you start a (inaudible). And so that's one of the areas that we're hoping that there will be some room for evolution along the

organizational maturity from before they have any kind of products out to when they have multiple products running. And the other thing is that as leadership changes over time there are some different ideas and some different preferences on which matrixes are really important.

Briefly just mention that the allocation of credit between leading and lagging indicators, it's important that we figure out a methodology to ensure that if a company has certain processes, and in fact, I think some of the participants here had said that before too, that if a company has these leading indicators upfront that they get credit for them and they start using them over time to generate the lagging indicators once the product is being out there and used.

And then I heard someone else earlier this morning talk about standard, the use of standards in market comparables. So if there's a company with a similar product risk type category or potentially customer type, if we can figure out how to leverage industry comparables to allow the younger startup

companies that don't have the products out there at the time of precertification that they would be able to leverage those upfront.

So thank you. If you have any comments or if you guys are a startup company we'd love to hear from you if you have other opinions. Brian is sitting right there, or myself, we would be happy to talk to you today.

MS. BAHR: Thanks, Anna.

(Applause)

MS. BAHR: Michael.

MR. KIRWAN: Good afternoon. My name is Michael Kirwan and I work for Personal Connected Health Alliance. So I'll call it the PCH Alliance as I go forward here. I'm their VP of Continua. Continua has been around for well over ten years now and they develop standards. So it's a very good segue from the last presentation.

But I would like to speak to you -- here it is. First of all, on your left is how Personal Connected Health Alliance and Continua have worked with the FDA over time. And, of course, we're really

excited about the precertification program because it gives us a way to help all members and anybody. We have members even in the pilot program right now, so it's very significant for us for that reason alone. But this is how we really tried to help with PCH or with the FDA over time. And you can see we've been involved and will continue to be involved.

We also had members, our members come together collectively and provide some feedback to the FDA and that's what you see on the right. So I'll talk a little bit more about this. But I'm really here about standardization. I asked the question earlier today, you know, how will the precert program actually encompass, you know, existing trade alliances, things like PCH Alliance that also have a certification program? And so what is significant here and what we realized many years ago is that we need to all get on the same page with data. At least take data out of the equation so you get the transparency, the quality and all the other things that come along with it, such as research evidence and big data, all right, and do it in a secure way.

And so this is what we've done and what we've seen and what has been somewhat of a detriment to our pushing this forward is that the consumer markets tend to change and move and we can't keep up. Well, now we're seeing a big influx going for Personal Connected Health Alliance and specifically the Continua design guidelines. They're freely available. Also going through compliance is free. We even give a Continua certified tool out, so we also enable, you know, possibility to being able to certify and be complaint to what are medical grade standards. So those are the same things, you've probably heard of HL-7 Fire or IEEE-11073 personal health device. Well, this is all the health medical and fitness sensing technologies that we've encompassed in well over forty different capabilities, well over forty different normal standards that we take and we refine those down so that it isn't negotiable. So that you can make certain that the data is very clear all the way from the sensor to the user to the clinician and into the EHR. And so I won't say much more about that.

But we have the five main use cases are health

and fitness, diabetes care, hypertension, COPD and then we're adding more. So we're really looking at digital therapeutics. We're really looking at all these other things that are coming out in the market. AI, artificial intelligence with additional automated speech recognition, making it frictionless. And that's the idea that we're looking for in the future. And we have, I believe, the scalability of building a data model for all of that and very quickly. So I just want to introduce you to that.

But for the precert program I really think that it would be a benefit to have third parties recognized in some fashion so that, you know, if they went through and did get continued certification, did use continuous code, we have what's called code for healthcare that automatically is compliant to the guidelines, if that were somehow recognized I think it would make it so much easier for many of the other organizations out here.

There are 160 manufacturing organizations here today. And I think this is a good message for you to take home that this does exist. And if we all get on

the same page and we do medical grade right and first and not consumer grade, keep it in mind, it'll make it a lot easier for you we believe in the future. So I'll stop there.

MS. BAHR: Thank you, Michael.

(Applause)

MS. BAHR: So now is the time for everyone to queue up for questions. We actually don't have that much time, but we'll take a couple of questions before the break. Anyone? David, I can always count on you for a question.

DAVID: (inaudible)

MS. BAHR: No, no, that one. Looking at him. So we are going to go fifteen minutes. So our panelists went pretty quickly today. Because I only gave them five minutes anticipating tons of questions. So if I had given you an extra minute what else would you have added to your presentation or what you would want to share with the team here and online that you weren't able to do it because I cut you off? Anand, you want to start?

MR. IYER: No, no, Asif is going to go first.

He’s really going to go first this time.

DR. DHAR: Yeah, exactly. Well, I would say that I think the longest pole in the tent is the regulatory science of the real world data and evidence. And I think that’s quite pivotal. Because if it is indeed possible to have let’s call it an agile regulator process where there are certain circumstances that indeed shouldn’t involve a huge amount of regulatory review upfront because in general the clinical scenario or situation really isn’t that dangerous and the current state of affairs with paper and memory is actually very dangerous.

Let’s say hypothetically that’s the situation. The type of data and evidence that one might need in that setting could be very, very different than let’s say an AI solution that’s deployed in a clinical scenario where physicians no longer have to determine if you need TPA and that happens in an automated way. Well, that’s a lot more dangerous a process. And so establishing the real world evidence and regulatory sciences of how much evidence, when, where and how, I think is an incredibly important topic. And it takes

work, it takes everybody here to get through that. And I think it's quite pivotal.

MR. IYER: So if I have an extra minute. Tomorrow we're all going to send time going through nuts and bolts I trust. We're going to go through the next level down and we'll fill out, you know, scorecards and KPIs. And the probability that our diagrams of what we all think is the right solution there's probably going to be a high degree of overlap. I'll bet a large sum of money on that.

Where I think we need to focus on, and you heard it a little bit in the last panel, there's a little bit of healthy tension in the string here, is our own willpower. And where do we actually try this first and where do we deploy it fearlessly? Because there's a part of me that says if we don't, I don't see, as a diabetes patient myself, I don't see a way out of this mess. I really don't. We're being slaughtered by these diseases and the costs and everything. And so I think the biggest challenge for us collectively is our own willpower.

And let's not be foolish, to the lady from

AMA, let's not be foolish, let's not do things that are super high risk. Why did we pilot it there? It makes no sense. We should pilot judiciously and we should pilot in areas where we can show demonstrable improvement in cycle time, agility, business value, etcetera, without compromising, if you would, all the things we don't want to compromise, which is patient safety and good manufacturing processes.

So I think that's the struggle for me is who is really in it? Who really wants to do this and who is going to keep pushing this forward? As Bakul and Cathy and it's not just going to be them, it's going to be all of us. And so that's my shtick.

MS. BAHR: Thank you. Anna, a big one. Michael, you want to go next? MR. KIRWAN: Yeah, sure. Yeah, I definitely agree with everything that was just said. And I think this must be the diabetes table because I also have Type I diabetes and I have to deal with this every day. And I see the value of tracking information, but it's so hard. If I do want to track my information with activity, I mean I know it has a correlation. If I

want to track my activity or my diabetes based on stress or anything else those things need to be done and it can't be done if we're doing different things in different ways. So it's all about interoperability and standards in my mind. So I'll stop there.

MS. BAHR: Thanks, Michael. Zach. Or actually let me go to Anna first, then we'll finish up with Zach.

MS. LIBMAN: So I just have two things that I would want, that I would add to my presentation. One is the question about timelines. We're asked, okay, so now we're going to put in this precert and we're working through. Now we have, you know, we've worked through the QMS systems, we have them running. What is really going to be the difference in timelines between, you know, the current process of having to put QMS and go through the 510-K process to when we started looking at the precertification and potential of some kind of regulatory review? So as we're thinking about crafting these scorecards for the companies and then once those are established we go through the entire process, what are these timelines going to look like? That's the

next question that I'm hearing all the time from our companies.

And then lastly I just want to say, you know, the team here at FDA is doing a great job and they've been encouraging so many companies all the time to come and talk to them. And from sitting on the other side of the table that we have come and we have talked. It's been, you know, they are super receptive. They want to hear. They have been taking our feedback. So I feel like we want to continue working together and I hope everyone here feels the same.

MS. BAHR: Thanks, Anna. Zach.

MR. ROTHSTEIN I think I'd take two points to build off of with Asif and Anna. On Anna's point about timelines, and I think I eluded to this a bit in my presentation, I think we're at a point now where as the work progresses on KPIs and other organizational excellence metrics there's also a need to start really talking about what the program, the big program with a capital P, looks like. And to not only talk about the actual timelines to bring something to market, but also how does the post-market environment look? How does a

recall occur? How do some of these other fundamental aspects of FDA's regulatory oversight either change or not based on a precertification program?

The second piece, just to build off of Asif with real world evidence, I think is really interesting when you look at the types of products we're talking about. In the traditional, you know, hardware based medical device real world evidence needs to be reported back in some mechanism, usually by a human. These products have the potential to provide ongoing real world evidence throughout their use. And so figuring out ways to better incorporate that almost live feedback loop in the precert program I think can really help accelerate the opportunities that we ultimately have here with kind of reimagining a paradigm for software.

MS. BAHR: Thanks everyone. And we're not going to get into answering each one specifically right now. But I think just as a reminder, so today and tomorrow is going to be about precert. That's not to say that real world evidence and streamline review is right around the corner. I think Bakul and everyone

reminded you, keep the input coming, there is a docket for it. So even though we're not going to focus on it very much today and tomorrow, we need to start hearing all that input because we are going to deliver something or a product by the end of the year. So we need that feedback. So no answers today, but we'll get there. So, yes, yes, yes, yes to everyone. So we do have one question. Go ahead.

MS. PHILLIPS: Great. Thank you. Marla Phillips from Xavier University. Great panel. I think this complex challenge needs to be addressed from the diversity of stakeholders. And you guys have done a great job representing a lot of people. So thank you for doing that.

I have a concern about the discussion we're going to have tomorrow about KPIs and wanted the panel's, I guess, input on it. So I can't think of a single KPI that could be used to assess company to company to company, let alone site to site within a company. So we're going to be spending a lot of time tomorrow on exploring metrics that could be used to compare companies to assess risk. But, you know, what

is your thought on that? And then should we perhaps be spending time on what else could we use instead of metrics? The implications could be pretty dangerous when you think of unsubstantiated conclusions, unintended behavior, all that kind of good stuff that comes with metrics.

MS. BAHR: Yeah. Anand, you want to give it a strike?

MR. IYER: So it's a fantastic question, I'm glad you asked it. I think in many ways, if I put my twenty years of management consulting hat on in the past, it's very easy to come up with KPIs for any company because it makes sense internally. It's what you do and you title KPIs to some revenue or profit objective or whatever your objective is. I think an answer, not the answer, an answer for this is start with our stakeholders who are who in this equation? It's for sure the consumer and the patient. And it's for sure the healthcare team. And if we start by optimizing their -- and somebody alluded to earlier correct word, experience. And if we start by optimizing their experience, which is ultimately then

going to optimize what we want out of that, which is going to be better health outcomes, better engagement, etcetera, then you almost work from the end consumer, somebody said voice of the customer, backwards. If we get a really good understanding of what that is and then start to quantify that, those may mean different KPIs to different companies, but we're going to look at the commonality across that. Because at the end of the day a patient with ADHD here, or a patient with diabetes there, or a patient -- there's going to be some expectations around the usefulness, the ease of use, etcetera. And so maybe that's one way to think about it.

MS. BAHR: Asif, do you have anything to add to that?

DR. DHAR: I do. I do think there are ways to do two things, one, to develop KPIs that are meaningful and relevant, and two, to develop an audit sign so that those KPIs that are reported have both audit ability that aren't very burdensome. And we as a society spend a lot of time in trying to figure out some of that, vis-a-vi, our tax system. But let's not go into that

subject just now. I was hoping I would get a chuckle.

But the development of KPIs could be as simple as saying how many people have been injured, under what circumstance, how many, what's your total amount of complaints, management, over what period of time have they been unresolved? If you take first principles of what we're trying to asses and survey there are actually quite a few KPIs that are possible. And we've heard already today some folks have come up with more than a hundred things that you should do. Well, generally in things that you should do have a KPI associated.

I do like the idea and the concept of unforeseen consequence. Testing the KPI is an important process. So there is agile behavior you use when you create KPIs. You should test them in the real world so you validate that they're not having an unintended consequence by certain processes. But it's certainly a very doable process.

MS. BAHR: Okay, that's good. Thank you.

AUDIENCE MEMBER: The gentleman in front of the mic who's sitting on a white paper, is he available

after the session or will that be available, please?

DR. DHAR: We will certainly have it available on our website and we're going to submit it properly as part of the --

AUDIENCE MEMBER: On the docket?

DR. DHAR: Yeah, in the docket. So it will be available for everybody. As these things go, writing a white paper is kind of tricky because the pace of this effort is so fast that you write stuff down and then you see all the progress and you have to edit it. So we're going to take some of the feedback from this meeting and get a proper draft out there.

AUDIENCE MEMBER: Thanks.

MS. BAHR: Any last minute question or last question, Bakul?

MR. PATEL: Since we have time.

MS. BAHR: Tara just put up the five-minute, so --

MR. PATEL: I know. Oh, just --

MS. BAHR: But know that you're between us and a break.

MR. PATEL: I know. Between you and the

break. We'll get to the break quickly. The question came up earlier about creating collaborative communities. And the question came up about how can people participate and be engaged in this conversation? I want to raise that. I think this is an example of people walking up to me and saying, you know, how can we help? And I said go form a group and then come back with an answer. How many of you guys here, can I see a show of hands that either you belong to a group, not here, not belonging here, that you already belong to that you can actually form a group around and give us input to? Can I see a raise of hands? Great. I want you guys to sort of get us names of those organizations that we can then ask you guys to sort of form those groups and communities that actually can help us provide input. And I think we need those diverse perspectives for us to sort of hear in a collective way that we can engage in a much more scalable way. So I just wanted to make sure that that happens and we get that voice heard. Great conversation, thank you. And that's all I had.

MS. BAHR: Thank you, everyone.

(At 3:00 p.m., break in session.)

(At 3:20 p.m., session resumed.)

MR. VICENTY: All right. So I think we are about to get started with our final panel. We've actually brought in several people who've got a world of experience and knowledge with regards to these excellence models, right, the principles, the application. And what we're hoping to do is, you know, really gain a lot from their experience, cautions that we should be looking at. Where do these work well? How do we get to a point where we as an agency can really leverage something like this to provide the confidence that we need to be able to focus our activities and our reviews in a better area. And something that's a little bit more critical to, I guess, the safety and efficacy that was brought up several times in some of the earlier panels.

So without really in the interest of time I'm not really going to go through a lot of their bios. They're available. We've made them available online. But I'd like to introduce Kim Kaplan to start us off from the CMM Institute. So Kim.

MS. KAPLAN: All right. Good afternoon, everyone. My name is Kimberly Kaplan, I am here representing the CMMI Institute. So today I'm going to provide a brief overview of the background and evolution of the CMMI framework, lessons learned, its utilization and benefits and opportunities for CMMI in this digital health software precertification program.

Don't worry it's just a picture. But I'm sure you're all familiar with the blue screen of death. If this actually happened here it would be an annoying disruption to the conference. But when systems and software fail and other situations it can have much more serious consequences.

In the 1980s the Department of Defense was having difficulty selecting quality software vendors. So they contracted Carnegie Mellon University to develop a capability maturity model which they could use to assess the quality and quality and reliability of their software contractors. So Carnegie Mellon started the Software Engineering Institute and they released software CMMV 1.0 in 1991. Since then the model has been iterated numerous times and expanded to

other areas, like people management, supplier management, acquisition services, so on.

When the Department of Defense started requiring maturity levels for organizations other countries began to see CMM as the golden standard. And in fact, in India the software industry there decided and chose to adopt CMM in order to compete for business in the US.

In 2010 CMM all of the different models were integrated into the Capability Maturity Model Integration or CMMI as its known today. And in 2012 with all of the international reach the CMMI Institute stepped outside of the Software Engineering Institute and became its own entity. Since then we've released the Data Management Maturity Model, worked on two government healthcare initiatives and are slated to release CMMI V 2.0 at the end of Q1.

So what is CMMI? It is a capability improvement model that is industry agnostic and can be applied at any level of an organization. Used by thousands of organizations across the world CMMI has been leveraged to help those organizations achieve

their business objectives.

And who is the CMMI Institute? We consider ourselves the global leader in the advancement of best practices in people, process and technology. For over 25 years thousands of organizations in defense, software, aerospace, healthcare and so on have used CMMI, have earned CMMI maturity levels to prove that they are capable business partners.

So the model is intended to help organizations to improve their processes. But it does not prescribe how to do this. For example, one of the basic practices in our model is to develop a list of tasks. This could be done in Salesforce, Gera, Lean Kanban Board, a Word document, an Excel document. It’s really up to your organization to determine what makes the most sense to your business needs.

These best practices were developed by members of all industries, the government and members of academia. It’s intended to be integrated with already existing development approaches, such as agile.

So outside of just the model, CMMI Institute also offers adoption guidance for organizations looking

to implement CMMI, systems and tools to support those organizations, training and certification for a deeper understanding of the model and, of course, the appraisal method that allows organizations to benchmark their performance against the model at a snapshot.

So I've thrown around the word capability quite a bit. What does that mean? Well, we like to use McKenzie and Company's definition that capabilities are anything an organization does well that drives meaningful business results. We have organized the key capabilities identified in the model into four major categories, doing, managing, enabling and improving. You can see the core capabilities in the center and those break out into different practice areas of the model to the right. I want you to note that organizations do not need to meet every single practice area in this model. There's quite a lot of them. It's intended to be flexible so that organizations can choose the capabilities and the practice areas that matter most them.

Here are some examples of organizations that have leveraged CMMI in order to meet their business

objectives. Honeywell's Czech Republic location, for example, was able to reduce their number of defects and cost of poor quality. Unisys was able to reduce their estimation errors and rework. ChemTek able to decrease their nonconformities on product deliverables. CMN's increased their productivity. Maniacs increased on time delivery and the ability to hit their Sprint commitments. And Alliance was able to increase their on time and on budget performance while also increasing customer satisfaction.

So who is using CMMI? Well, lots of organizations across a wide variety of industries are leveraging CMMI. And a number of these organizations were recently listed in Fortune 500's top organizations. CMMI is used all over the world in over a hundred different countries with a majority of these organizations already leveraging agile methods.

Appraisals can be executed on organizations of all sizes. The method can be applied to an entire organization, a division, a project or even a team. Seventy percent of the appraisals executed so far have been in organizations with a hundred or fewer

employees.

So how does CMMI fit into this digital health software precertification program? Well, we've already worked with the Government on two other healthcare initiatives, the Patient Demographic Data Quality Framework and the Medical Device Discovery Appraisal Program, which you may have heard also called as the Voluntary Medical Device Manufacturer and Product Quality Program.

So in a 2016 survey it was found that 86 percent of healthcare practitioners either personally witnessed or knew of a medical error that occurred from patient misidentification. When patient data isn't prioritized providers can order duplicate testing, incorrect treatment or even make misinformed diagnosis. So the Health and Human Service national office for coordinating health IT partnered with CMMI institute to develop this Patient Demographic Data Quality Framework, which is intended to allow organizations to assess their data management against best practices, identify gaps and be able to develop initiatives and plans to address those gaps and continue to improve.

The Medical Device Discovery Appraisal Program or MDDAP is part of FDA's larger case for quality initiative, which is intended to shift the mindset of the medical device industry from one of compliance to one of continuous improvement. Over the better part of 2017 we developed this program and defined the processes for the exchange of information between medical device manufacturers, agency and CMMI Institute. What you see behind me is a high level flow of this process. It also indicates what's expected from participants and when and what FDA is providing and when.

So I know in the breakout sessions tomorrow we'll be discussing what kind of data can be collected, shared and maybe benchmarked. So I won't get into too much of this detail. But I wanted to show you on the left-hand side it is an example of a scorecard that an appraised organization in this program might receive. This is a tailored version of the model. It's been tailored for this program. And in the lower left is an example of some of the accumulative results that an organization might see and be able to compare

themselves to. On the right-hand side is the overall percentage for that specific practice and then for the overall organization.

So one of the things that we're trying to do, I want to reiterate that this is still a pilot program. We've conducted six appraisals, we have ten more scheduled and we're hoping to conduct thirty in 2018. Because this is a pilot we're going to continue to learn. And we've set up governance meetings so that we can have these conversations with medical device manufacturers, Agency and lead appraisers. Thank you.

(Applause)

MR. VICENTY: So I'd like to bring up Tim Anderson, if possible. And he's going to really share something that we've come across in leverage because I think it really helps paint a complete picture too in terms of the EFQM model. And I'll let him go into a little more detail on that.

MR. ANDERSON: Good afternoon. It's been quite a day, I've enjoyed it. And I'm going to adjust some of my comments because coming into this I was absolutely impressed with how far FDA and the

stakeholder community has come on this process.

So a quick history of EFQM. Ironically it was an American who went to Japan by the name of Demming post World War II that shook the world in globalization. Became a reality when the Japanese came back and said, hey, we can build better products than you now. And the response was Malcom Baldrige and then shortly the European response the EFQM.

So where is EFQM now? We have a global footprint. The six starts represent the offices. Everything in orange and yellow represent different partnerships. The great thing is, is you see five white circles in Latin America and you see a couple in Asia. This is where the Malcom Baldrige and the EFQM have come together to create national awards.

So what is excellence? It’s all about sustainability and stakeholders. How many people in here have a boss? Let’s see hands. How many people in here have a boss? How many people in here have a significant other?

AUDIENCE MEMBER: I have the same person.

MR. ANDERSON: Okay. Oh, the same person.

Okay. So excellence is all about managing these expectations. Do these expectations ever change? They do. So this is what's important in an excellence model and in your approach to excellence is that your stakeholder connections are real time as much as possible.

So there is three components. On the top you have what's called the fundamental concepts. These are really the values, the core values of the model itself. Some people ask me which is the most important. Values don't work that way, right. So the way it works is that if you have a deficiency, you know, you're doing really well in one area and not so well in another it's called the law of weakest link. So what you need to do is you need to bring all of these things up to the same level and then raise the bar together.

So how does that match up with the FDA current approach? So when we look at the excellence principles, the FDA excellence principles you'll see that the only deficiency explicitly actually within the EFQM model is in the cyber security area. So that little gray box in the middle where the X is. So it's

a holistic approach that if you decide to use an excellence model it would be congruent and compatible with the FDA approach.

This is the third component which is called the EFQM model criteria. So on the left side you have enablers, okay, this is what you do. On the right side you have results. This is the results you get from what you do. Makes sense, right. So are we supposed to focus more on what we do or the results that we get? And what we find in excellence models is typically it's a 50/50 balance. And this is true with EFQM. So what you do and the results you do are equally important.

What does that look like from a practical standpoint? The structure in the enablers, this is an example from leadership. There's the criterion level, at the criterion level it's a strategic overview really of the context that leadership should be in. And the criterion part breaks that down really into a management level, review type level. And then the guidance points those are really at the operational level. And the guidance points, similar to CMMI, they don't tell you what to do, right. You know, this isn't

what you should do or how you should do it, but this is really this is where you should look. These are the things that you can consider in order to be an excellent organization.

So the structure of the results criteria, the results there's four results areas currently. The model is actually in 2018 is going through its next iterative process. The structure you have the criterion parts are aligned according to the KPI structure. So if you look at this you'll see on the right side, on the far right, 6A, 7A, 8A and 9A, those are your high level objectives. In other words, and they can be in matters of perceptions and also in matters of performance. And these are really the final results. In the middle column what you'll see is these are the performance indicators. So these are the things that should be a well-defined comprehensive set of predictive measures that gets you your end results. So many organizations actually do very sophisticated analysis, is what we're measuring actually giving us the results?

So radar, radar is our version of PDCA. Okay.

For those of you in the room that know what PDCA is, plan, do check and adjust. We have our version of it and it represents, the acronym presents results approach, deployment assessment and refinement.

So from a structural standpoint each enabler has the same approach. So you have the approach, the deployment, assessment and refinement is the element. And then you have the key attributes for each of those.

From a scoring methodology perspective you see that there's a hierarchy. So in the scoring methodology itself the hierarchy goes from the top of the page through all three of the elements. So it's weighted heavier on the top basically than it is at the bottom. And also there's a secondary hierarchy and that's within the element itself. So for instance, in approach sound is more important that integrated.

So as you look through this it becomes the limiting factor. And it makes sense. So imagine that you have a well-defined approach and you've implemented it across the entire organization, but you don't have any understanding as far as really is it effective. In other words, the approach itself was bad. Should we

give you credit for anything more? No, it doesn't make sense. So results is exactly the same structure. Identical setup, only there's only two elements. And the scoring is the same approach.

So what do we know? We know that leadership is the key variable to success. In every instance we find that where there's long term leadership commitment excellence works. And this is true whether it's CMMI, whether it's Baldrige, whether it's balanced scorecard, leadership commitment on a long term basis is the key variable. And you can look at the results and see that over time it makes a difference.

So once again, I want to congratulate FDA in terms of how far they're pushing the envelope. It's a fun and exciting conference to be a part of, workshop. One of the biggest things that excites me is how it can add value to the stakeholders, but how it's going to impact healthcare, I think, on a long term basis.

The challenges. I think the challenges are perceptions. I think a lot of that's been talked about. Perceptions about the approach, perceptions about the organization. And FDA has got to kind of

step up to the table and use excellence themselves. So I hope that this has helped you get an overview of EFQM and enjoy the rest of the afternoon.

(Applause)

MR. VICENTY: Hopefully there will be some time and some discussions during the Q&A. But I'd like to bring up Kirk Holmes now. Kirk Holmes has got a background with Baldrige. And I think he's also had some experience with us and shared some insightful points of watch outs that we should be keeping an eye on. So I think he hopefully will share that again.

MR. HOLMES: Thank you, Cisco. And thank you FDA for this session, it's a great session. Very enjoyable to be here again. I spoke about a year ago to the MDIC about metrics and how some lessons learned from the Baldrige program. And as he mentioned this kind of takes me back about twenty years ago, I was involved, I worked for SRA and we held the first contract to the FDA for the automation program. It was the first automation program that the FDA funded using PDUFA, the Prescription Drug User Fee Act. And it was the beginnings of electronic submission, it was going

to change the way the FDA did business. And it did change the way. And I remember working on a project Pre-Approval Inspections. So it really takes me back when I see now working on the same kind of issue, but in the modern age when so much has changed.

So I'll talk a little bit about Baldrige. I'm going to take a little bit of a different tact, because we only have about ten minutes to talk. So I wanted to try to focus on some of the things that I would suggest as takeaways. Because my background is actually not just Baldrige. I was asked to speak about Baldrige, but I just wanted to give you a sense that I've been using Baldrige since the 90s. And I first was using it as just a tool. I was in software development myself. I was managing a group for an organization, which was a very proud holder of CMMI Level 5. And the program manager was very happy to continuously remind me of that. When I learned how to use Baldrige as a tool for improvement I discovered the program was having issues, he disagreed because he was CMMI Level 5. And the program did actually get cancelled, so there was a lot of lessons learned to that $5 billion debacle. But I'm

a big believer in all of these frameworks. To me they're all just tools. So everything I talk about I'm going to try to put it in a context around how -- what kind of things you can think about and how there are tools to help you move forward.

So first off all though I will give a little bit of background about Baldrige. How many people are already familiar with it? Can you raise your hand if you're familiar with it? Okay. Maybe about a third or half of the audience. So not going into as much detail, but I will say a lot of the aspects of Baldrige are similar to what Tim described, so I didn't want to go into all the details. But there's seven categories in Baldrige, leadership, strategy, customers. And for each of these categories, just like Tim described, there is questions and details around here are the elements that are important for excellence and for producing results.

The concept is very much a left to right flow in that as everyone says in every framework there is it starts with leadership and vision and so forth and then eventually you get to results. The other key thing

about Baldrige is that there has to be integration between all these components. And I'm going to come back to that theme many times.

And the other part about Baldrige that's not pictured here there's the core value concept and those underlying core values, but it's also the concept of an organizational profile. And I'm going to talk about that a couple more times, which is that this is all in the context of where you are. And I think I heard somebody this morning make that reference too is where the organization is. Every organization is not the same.

But with these categories one of the big lessons learned for me is that it helps you understand are you hitting all of the elements that are needed for excellence. And there can be weak spots in any organization. Everyone I've ever visited there have been weak spots. And so how strong, for example, is your knowledge management? Do you have the specific practices that you need in order to manage that? So a lot of those elements show up in almost all the different models. They have different aspects of

knowledge management and process management and so forth. Baldrige just categorizes them differently.

One of the things though about Baldrige that's very, very structured is the stuff on the right. When we do examinations and reviews of a Baldrige applicant we look for the process areas, in the process areas everything except results. So all those process components we look at approach, deployment, learning and integration. And it's a very systematic evaluation. That makes it easy from a review standpoint. And to me I think it has implications for what you all are trying to do in this environment and the relationship between industry and the regulators is that how do you systematically give yourself the confidence that the approaches being used and the processes will generate the results that are needed. And they're not just needed for business reasons. They're needed because frankly sometimes people's lives are at stake. So this is big stake stuff.

And we use this systematic approach in Baldrige to always ask the question, okay, you said you have an approach. Is it fully deployed? And going

back to what I said before, it's the issue of context. It depends on the organizational context. So if you have a very largely dispersed organization that's global and all these different pieces of the organization all participate, deployment is a much different issue than if you're -- all the people are sitting in one building in Silicon Valley working in cubicles sitting right next to each other. So you really have to understand that context.

Integration is the other piece that going back, how do you ensure that we went from good to great? Or if you're in a very much life critical situation, how do you ensure that things never go wrong, where integration can become even more important. I'll give you just one quick example. I went and visited a company that they had written an application trying to win the Baldrige award. They were a very high score, had won the award before. And it was a hospital system that I went and visited and the integration was incredible. That you could go to any part of the organization and all those seven categories everyone understood how they all fit

together. You know, the guy who's mopping the floor understood how his scorecards for the way in which he mopped the floor related to the safety indices that were part of the strategic plan that were being measured at the corporate level and the Board of Directors was following. And everybody understood it and it was all very tightly and the most -- if I ever get sick I'm getting on an airplane and flying to that organization to be taken care of. So that's very important.

The other thing I like is the adaptation. There's been many decades of Baldrige being applied in healthcare in particular, so there's a whole criteria of framework that's been adapted for healthcare. Because a lot of people learned, well, how do you apply this to healthcare? And it's also been adapted to cyber security. Healthcare I'm really excited about because out of the last 22 winners of the Baldrige award 10 have been healthcare organizations. So there's a lot of traction in the healthcare environment and a lot of learning that's gone into that.

If, by the way, you're interested, someone

made a comment earlier on a panel about transparency. One of the things I like about this program is that you can go to the website, the Baldrige website, look up the award winners and you can pull the application that was written by some recent winner. Some hospital system or some chain or some manufacturer and read how do they approach leadership? How do they engage their employees? How do they monitor their effectiveness?

So that was the process side. Then there's the results. For the results we look at four different characteristics. And this is very similar to what you saw in the EFQM, but levels, trends, comparisons and importance. So everyone understands levels, right, because you have to be good. You have to have a level that's, I mean, no matter what if you put out buggy software that's not good. Not good enough. But it's not just the quality level, but of course, it's the trend because this whole system is about how do you get the confidence from a regulatory standpoint and from a business standpoint that success today will mean success tomorrow? And so I was getting the trends and then the comparisons.

And the other one is really, really critical. In the Baldrige world we learn about the importance of segmentation and importance. So the measurements and, again, going back to context, what's important for what you're doing? So I have reviewed applicants who talked about the results. But they said, well, strategically it's really important that we penetrate a particular market or that we -- we had this big strategic challenge with some of our far flung locations. Or one of the plants is located this far away. Okay. So show me the measurement that you've accomplished your objectives and you've overcome that challenge. And getting to the important measurements is so critical and it's always going to be in the context of your own organization. Big lesson learned.

Five general aspects to results, very similar to a lot of others. The only point I make here is that if we had more time to describe it, these map to some of the central -- the things that are being used, the elements of quality for this initiative. But what I always talk about is the need for self-balancing and self-adapting and self-correcting, which is that you

have to be able to adjust the balance between these factors and it has to be relevant to your own organization.

The couple of examples I'll give too is based on the current technologies and the trends. I think about organizations where a couple years ago -- I do a lot of work with CIOs and IT organizations and ITIL and needing process around change and configurations was really important. But then nowadays, of course, if you have to have massive scale you have to worry about things like how fast can you deploy and how much do you automate? And now you don't necessarily have a structure and as methodical management of change, but your process has to be adapted, it has to be updated. And what I would look for from an oversight standpoint then is, well, do you have a process in place to keep up with those changes, keep up with the evolution and to make sure that you're balancing those needs correctly. And that's hard to do. Some organizations that I've reviewed and examined they have done that well and some have done it poorly. Sometimes they're big organizations and sometimes they're small. It's

not size, it's just how well you execute.

So that's my lessons learned and be happy to take other questions and comments.

(Applause)

MR. VICENTY: And I think one of the things that helps lead up to the discussion we're having tomorrow is really how do we take all this and make it something that we can align and visualize. And I think I'd like to bring Howard Rohm from the Balanced Scorecard Institute to kind of go through his slide deck and really what the value of that is.

MR. ROHM: Good afternoon, everybody. I'm almost the last event before dinner and cocktail hour, so I will try and motor quickly through here. I'm the Co-Founder and the President of the Balance Scorecard Institute. We do a training certification and consulting on the balance scorecard systems, KPI development and strategic planning and management.

When I looked over the elements the first thing I thought of where is engaged leadership, which is one of the key components of any management system. By engaged leadership we mean leaders at all levels in

an organization that solve challenges. They eliminate problems. They eliminate resistance to success and to excellence. They live the behaviors that we'd like to see from all of us in an excellent organization.

Some key questions that I think we should focus on, what are we trying to accomplish and how will we know we're successful when we see it? I'll keep coming back to that. Because one of the premises that we have when we build strategic management systems is to start with the end in mind and work backwards. That's harder than taking the easy stuff and working forward. But I think you'll see why we do it that way here in a moment.

When I think about translating the principles into what it means for an integrated management system I look at something like this. We want balance between those elements. We want to be able to measure the important stuff, not measure all the easy stuff. I heard somebody earlier talk about 100 measures. What I want to share with you is how to get down to the 10 that matter, not the 100 or 200 that you can collect by sitting around and saying what should we measure?

That's the wrong question. The question really is what are we trying to accomplish and how will we know we're successful when we get there? So working backwards from the end.

We want to build individual and collective accountability with this management system so that it's baked in. So that culture and changing hearts and minds is part of the development process. It's not a hood ornament that we add on at the end of the development process. It doesn't work very well like that. And we want to have a system that aligns vision and mission and core values and strategy and the operating programs that the organization does and aligns employees so they can see how they fit in with the picture of the future, the shared vision of the future.

Balance Scorecard has been around for over 20 years. In the early 1990s developed at Harvard by two professors. The original idea was to take a -- find a way to develop a measurement system so that put more emphasis on non-financial performance measures. So they came up with this idea of something called the

learning and growth perspective. The four columns here are what we called perspective, they're dimensions in a balanced scorecard system. Financial, customer, internal, we know how to measure those. We've been measuring those for decades. And in the case of internal processes, you know, 100 years or so. But learning and growth was new. It was the human capital, the infrastructure, the tools and technologies, the corporate culture. How do we measure that today as a leading indicator so that we can get some insight into driving future success tomorrow?

The problem with most of the early scorecards and there are still a lot of them floating around, is they tend to focus on the easy measures. You know, just get the measures we have, let's dump them into four categories, claim we have a balance scorecard, claim success and march on. A lot of the calls that we get around this, I have a scorecard, is it really giving me what it was designed to do?

The 21st Century version of the balance scorecard is an integrated strategic planning and management system. It starts with organization

assessment internal and external, the SWOT analysis, the enablers and the challenges that we face in the marketplace. We use that to drive the customer value proposition discussion to develop a strategy. To make that strategy communicable and clearer so that people up and down the organization understand what we're trying to do with the organization and how they fit into that.

Strategy is a path and a plan. It's a way of getting from where we are today to point B five, ten, fifty, a hundred years in the future. That's that shared vision of the future that drives organization success. Once we have the principles of our strategy development we can use that to influence the financial budget forecasting process, financial planning. We have a strategy input to financial planning.

That also helps us with the managed personnel. We can cascade the scorecard to align individual descriptions and the critical success factors for individual employees to the vision, to the shared vision of the future. So we have line aside alignment.

Having a strategy, a corporate strategy helps

us to build what we call tier two and tier three scorecards where you have use strategy to drive the development of the operating plans for your divisions and your departments. And then use how employees fit into those departments for what we call the tier three scorecard.

Finally, we have a feedback loop. We execute strategy, we measure the results and we turn that into information that we can use in the next planning cycle. So it’s really a very holistic way of looking at an organization as more than just a set of performance measures. We had a discussion earlier about how do you get to excellence? I will suggest to you that you get to excellence by thinking through various steps similar to this that help you define what excellence means in your organization. It’s about alignment. It’s about clear communication. It’s about measuring what matters. It’s about acting on performance information to better informed decision-making. And it’s about quality and timeliness and service and so on.

Today’s version of strategic planning looks something like this, strategy is about altitude. When

we talk about the high altitude we're talking about who are our customers and what do they need? What is the market within which we have to operate? We look at mission and vision. Mission is our purpose, vision is our shared vision of the future. The balance scorecard perspectives give us those different lenses that we can look at our organization with. What I'm sharing with you, by the way, applies equally well for private sector for government and for not for profit. And it is very scalable. The smallest organization that we built a balanced scorecard system for was seven people. And the largest is 140,000 in the association for Speech, Hearing and Language Association in the Air Force.

Strategic themes and results, strategy derives from mission and vision. It's the pillars of excellence that make up our organization and it goes all the way through the organization. Strategic objectives are the DNA of a strategy and they allow us to use a common language. Words matter in this business, so we all use the same language. And have a holistic way of communicating with people up and down

the organization.

Notice where performance measures and targets are. Performance measures are a means, not an end. So if you're going to do KPI development and look at the performance measures that matter most to you, start with something else. I've been doing this for 40 years in about 40, 50 countries now. And the one shared experience I will give to you is if you're going to do KPI development don't start with the question what should we measure? That's the wrong question. Start with the question what are we trying to accomplish? And get the smart people in the room, have a facilitated discussion about accomplishment, a strategic conversation. You will not find your measures in a book. You will not find your measures on the internet. You will find them in strategic conversations with the right people in the room. That's how you get to the few that matter rather than the 500 that are in a book or on the internet.

Last step strategic initiatives. Now that we've broken down things from high altitude to low altitude we can start connecting the dots. What we

want to do is identify those critical projects that are important to, what, to getting our strategy and being successful in the marketplace, or if we're a government agency with our mission. We flip mission and vision if we're doing private industry. Most industry is vision driven. Government, not for profit are primarily mission driven. That's the strategy formulation part.

So let me take just a minute and talk to you about the perspectives and the balanced scorecard. There are four of them and we named them differently depending on the uniqueness of the organization. So this is sort of the generic school solution that I'm sharing with you.

Financial and stewardship, financial for private business, stewardship for government and mission driven. In the case of stewardship it's effective use of other people's money. Taxpayer's money through government agencies. Customers and stakeholders you start with the customer value proposition. What do they need, what do they value? How do we ensure satisfaction and retention? Internal business process perspective deals with efficiency and

quality and timeliness and safety.

And finally the fourth perspective is what we call the organizational capacity. What Drs. Kaplan and Norton at Harvard called learning and growth. It includes human capital and tools and technology that we use, the infrastructure that we use. The culture and the capabilities of the organization. All this stuff has to have a home. If you're going to build a high performance organization aimed for excellence these kind of important elements have to have a home and they have to connect so that you can communicate with clarity to the folks in your organization.

The logic behind the balanced scorecard is simple. If I can improve organizational capacity and capability I'll be able to have more efficient processes. More efficient processes will lead to more satisfied customers and stakeholders, which in turn will lead to financial rewards for the owners of the business.

Again, if we're a government agency we put stewardship first. Because what I have just described to you is a pictorial way of looking at a value chain.

So the ultimate question is who is the value for? In the case of a government agency it's for the citizens, it's for the war fighter. In the case of a foundation or an association it's for the members. So the logic tracks who the end customer is and how they perceive value.

I think a good way of looking at how this stuff fits together is think about building a custom house. The floors of your custom house are the perspectives in the balanced scorecard. In the roof we have the high altitude strategy stuff, vision and mission and core values, customers and stakeholder value. Enablers and challenges that come out of the SWOT analysis. We have strategic results, or you might call them strategic goals. What we translate strategy into. The load bearing walls of the house are the pillars of excellence in our high performing organization. I've listed four here. We've taken some of the largest organizations that we've work with and we can always get down to three or four strategic themes or pillars. If you get too many more it gets very complicated.

I remember I used to work at the Department of Energy back in the day and we once had a strategic plan with ten pillars. Completely unmanageable. Completely unmanageable. Impossible to communicate clearly to the folks down the line. So if you're going to do this, you know, keep it simple.

Engage leadership. Interactive communications in our core value, they're foundational, right. They're the foundation that we build the house on. Again, if we're doing private sector versus public sector customer stakeholder we'd flip that floor for a government organization.

If you look at what we just heard from Baldrige criteria you see a lot of the similar things. The balance scorecard is a way of taking Baldrige or EFQM or CMMI, taking those outputs and put them into the context of a strategic management system for the organization. These models are very complimentary.

So for the long term, engage leadership, change management, incorporate it when you're building the system. Incidentally when we recommend building these systems it's with different voices, shared voices

from the organization. This is not a job for the senior executive team to build by themselves. This is not a job for the head of strategic planning to do by herself. This is where you want to build in individual accountability and collective accountability right in the process of building your management system. That's the most effective.

So let's take a look at a powerful tool that might help the FDA here get to its end result and a shared vision of the future with the private industry. This is a picture of a strategy map. Arguably one of the most important contributions to the science and management in about the last 20 years or so. The perspectives are the rows. We call the top two perspectives the results perspectives, financial, customer stakeholder. The bottom two perspectives, internal business processes and organizational capacity. They are the driving perspectives.

The lines, the connections always go up. This is a cause/effect logic diagram. It's not a process flow. It's not a systems diagram. It is a logical connection of how an organization creates value. The

ovals are strategic objectives. They're continuous improvement activities. The logic is if I can do better at just one strategic objective that's connected to another I should see some effect as a result of that.

How do we get this? We have strategic conversations with folks. And you can see if the if then logic will work up through the value chain. It's hard work to make one of these maps simple and easy to understand. And this is where getting the right people in the room and having a facilitated workshop will help you get to the end.

I've added in safety culture as a strategic objective, reducing risk to improve patient quality of life. There's a logical connection between what we do in the shop floor and how satisfied our patients are going to be at the end of the day.

Let's talk for a minute about KPIs, how you actually develop them. That will give you a replicable way of doing it over and over again. There's a family of measures. You can't look at KPIs as just let's do the KPIs. We're interested in strategic measures.

There’s different type of tools. Okay. We’re running a little late. Product and service measures, project measures, employee measures, risk measures. We have different tools for dealing with each of those different categories. The goal is to pull from those, use your performance measurement stethoscope where it makes sense and then pull out of that public information and private information in your reporting system.

Steven Covey was right, start with the end in mind. I suggest that you start at the right with the outcomes and work backward to the left, rather than do the easy stuff, which is to start at the right and work out. Business intelligence goes up when we start talking about outcome measures. Finally, you can drill down on your KPIs. You go all the way down to the shop floor and that’s what you get with the cascading and the balance scorecard. Performance measurement systems give you the ability to do exception reporting. Get that information to all your devices, different forms.

Here’s an example of a one-page balance strategic plan where all of those strategic elements

are put in one plan. There's a bigger version of this in the handout or in the file that's available to you. But you can see the perspectives, the objectives. The KPIs associated with the objectives.

We're measuring corporate strategy. Targets and thresholds are set. And then the performance strategic initiatives over on the right are that set of critical projects that help make strategy actionable. For example, in the internal business process perspective a lot of times we'll see the result of Baldrige initiatives based on their assessment. We have to fix these processes. We have to improve this quality. Those tend to make it under the corporate scorecard as critical strategic initiatives.

So how can this help you? I just did a little brainstorming here. I think what we're looking for is a bridge between the way private industry views things and the way government views things. So one way you might do that is to build a common strategy map. Come up with a set of objectives looking at it through the lens of the government's view and through the lens of the private sector's view. Much like Walmart does with

their vendors and suppliers. The Walmart balance scorecard is aligned with supplier balance scorecards who are providing services. And you essentially create a common language using the strategic objectives, which are those DNA continuous improvement activities that cause an organization to strive for excellence.

So in closing I would pose the question, how can we ensure patient safety by creating a more efficient and effective process that balances and aligns the FDA regulatory interest with the financial and other interests of program companies? And I leave you with a parting thought that getting to excellence is a journey, not a project. It takes time. It's worth the trip. People get smarter, people see how they relate to the vision and it is a strong step in the right direction. Thank you.

(Applause)

MR. VICENTY: So thank you, Howard. So now I think we've got a little bit of time. No? Yes? Maybe? Okay. Let me see what I've got here. For some questions, I've got some available here for the panel. But I'd like to open up, if anybody's got any real

specific questions or insights that they'd like to share, much appreciated. I'd like to actually just start with the question that was asked earlier, do a little bit of ad hoc from the ones that we've got here. But someone I think online earlier, Zach brought it up, and I thought it was a perfect question for this panel. You know, the discussion was why don't you just pick an excellence model, there's plenty of them out there, and use it? What would be the impact of that? And I think it would be a good opportunity to kind of throw that question to the panel here and get their thoughts and insights.

MR. ANDERSON: I think that first of all it would add a burden into the process. Number one is you would be required to maintain that and improve it on a basis that maybe almost impossible to do. And every organization out there needs to pick what works best for them. And there are so many. I mean I was introduced to models that will help you succeed today that I didn't know about in the medical device area. Fantastic. And I think that in the same way that you're engaging the entire stakeholder community it

would slow down your ability to innovate, to be a mandate.

MR. HOLMES: I'll say that I've thought that at times. But on the other hand I will say that I've seen some success, like I mentioned healthcare, where it hasn't been a mandated approach to using Baldrige. But it gives a common lens that many organizations can use to compare. And it's only for comparative.

Because what I believe firmly with the same thing that Tim just said, that ultimately every organization has to drive in its own context what works for them. But what happens is that you can still have a common element that is used to compare organizations and at least see how you can collectively raise the bar. And I've seen that happen in that healthcare arena and I think it could, as long as you still have flexibility within your own individual organizations to pursue the improvement using this whole set of tools.

Because I'm pretty sure that there are very few organizations that only use one approach. Every organization applies for the Baldrige. When they answers they talk about how they use Balance Scorecards

and how they use process frameworks like CMMI or ITEL if it's IT and Project Management. And so all of those things still end up getting used. But the question of could you have a common lens so that just like they do in Baldrige you could then publish them and then learn from, well, how did you approach that problem? And then we can all raise the bar collectively. That could be powerful.

MS. KAPLAN: So I think there's a lot of concern that by choosing any one specific model it's going to add a burden or an extra level of compliance requirement to anyone who wants to participate in this program. So what we're trying to do here it seems is look at all of the places where these models overlap and pull the best pieces from all of them. And in doing so creating another model. And all of these models were originally created for similar purposes, to help organizations improve. So I think a lot of it depends on what exactly it is we're trying to do in this program and how we can tailor whatever we do to decide that will benefit all of the participants.

MR. ROHM: Yeah. I was in the Pentagon the

day before 911 and I was talking to -- they had a strategic planning for the Secretary of Defense. And we were talking about goals, goals, goals. And I went across the hall to one of the services and we started talking about objectives, objectives, objectives. And it took me about 15 minutes to realize that they were talking about the same thing.

I think more important than the model you choose are the words that you used. I think getting agreement on a common language is absolutely critical with the number of companies involved the Government. If you get that right --

Rice University did a study, oh, a decade or more ago looking at all the different models for performance measurement, management, budgeting and so on and they came up with about 143, if I remember correctly. I'm embarrassed to tell you that I've worked on about 35 of them over the course of my career. And, you know, it's more a case of, again, start with the key questions, right. What are we trying to accomplish? How are we going to know success when we see it? What is the common language that we're

going to use so we can talk to each other through the lens of efficiency and effectiveness and excellence. Define what that means, you know, at the front end. And then, you know, I wouldn't be so hung up on which is the -- trying to find the ultimate model. I think that's probably not worth the time.

MR. VICENTY: Take a question from the audience here.

MR. LOOK: Thanks so much for this great overview of these models. Howard Look from Tidepool. One of the things that I think a lot of us are hopeful about with the precert pilot program is that we'll end up with a framework that will be attractive to startups and to entrepreneurs. And the ability to say, yes, I am an organization of excellence, principles even though I'm a startup will be something that will compel people to get into the field and innovate new things and new innovative technologies and therapies that are good for the public health.

I'm curious from each of you which of these models do you feel like are especially good or what elements of your models are especially good and have

been shown to be successful for a startup who in their first year or two or three is making hundreds, if not thousands of decisions every week and trying to iterate and be agile in a lean and agile startup environment.

MR. HOLMES: I'll start. I believe they all can be useful. Because in my experience, again, if you, for example, if you adopted CMMI there are parts of CMMI that ask about your leadership and how you approach things. And you could very well use elements from Baldrige or from Balanced Scorecard to address those or vice versa. If you use the kind of framework as your guiding framework, like the Balanced Scorecard you would still have to address how you're going to make some of these things happen and fill in the gaps.

So in my personal experience I have seen any of these approaches help small companies as well as large. And then I've seen small as well as large fail miserably in different areas because of things they weren't doing that were fundamental. And it all comes down to execution and it can definitely be useful for small or large in my personal experience.

MR. LOOK: Are there some examples of startups

that you say they crushed it, they used this model or that model and --

MR. HOLMES: I know small organizations that launched new services that have used Baldrige as a framework and built around that relatively small. And I've known that have used CMMI and a structured process like that. So, yeah, I would say that there are some examples out there. I'd have to get back to offline with some names if you wanted any.

MR. VICENTY: Kim, I know we've tackled this question a few other times too, but Howard go first.

MR. ROHM: I think it's how you structure the conversations more so, again, than the model. You know, what we found out with the Balanced Scorecard is that if you organize workshops, strategic conversations along a path, we start at vision, we'll start at high altitude in mission and core values, then we'll drop down a little and we'll talk about core values, you know, and then we'll start talking about strategic themes and strategic goals and results, if you organize the conversation in a disciplined way what we've found is the dots start to connect. You can take the output

of that first conversation, it becomes the input to the second conversation. So I think it's much more about putting some discipline and some structure around the smart people that you have in your organization to get at those kind of strategic elements.

There's a little over a dozen of those elements, if you counted as I was going through, that are critically important to a management system. And then when you get down to the tier two, you know, make sure that you involve different voices of the organization in those conversations. The worst thing you can do is adopt today. It may have worked 40 years ago, but today adopting command and control is a recipe for failure. And if you build the system with the people who are ultimately responsible for accountability for results they have ownership in it from day one. And to me that, we've seen that to be much more important than, you know, which version of the Balance Scorecard truth do you believe in? I mean that's the wrong conversation to have.

Good folks talk about vision. What do we believe we want to be when we grow up, right? How are

we going to get to someplace else ten years or twenty years or fifty years from now? Let's have that conversation regardless of what we call it.

MR. VICENTY: So, okay. I know that -- and just to follow up on Howard's question because that's come up a lot, right, is this only applicable for the large manufacturers? Is it applicable for small manufacturers? And I think heard the theme of integration happening a lot in both of your discussions. And the fact that sometimes within even a small manufacturer that happens better and easier than we see at some of the large ones. You know, I'd like if you've got any comments on that from the experiences we've had and then, you know, follow up from Kim on it.

MS. KAPLAN: Sure. So just to the questions now about rephrase for smaller organizations and how this can apply. So I know that this is one of the areas where the CMI in the past has had some struggles. And we've heard that from our customer base and our end users who have tried to implement CMMI thinking it's a lot of information, a lot to go through. So and our newest iteration, which is slated to come out in March

we've streamlined the way that the approach can be implemented. We've created -- I can't speak to too much of it yet, since it's not released. But we've streamlined the approach. We've created adoption guidelines to help smaller organizations in particular to be able to understand sort of the basic things that they could leverage most easily and most effectively for their organizations.

MR. VICENTY: Thank you.

MR. ROHM: It tends to go a lot faster with small teams. But the process is the same, you know, it's those critical conversations and making sure you touch all the strategic elements on the way down so that you have a shared collection of what those things mean and more importantly how to communicate to everybody who's not in the room. It takes two to three months to build a system like this for a very large company. It takes four weeks to build it for a, you know, 12-person company. So you see time savings like that. But they're not terrible significant. It's more about getting the right people in the room and getting it done with high energy. You know, get it done quick.

Get it 80 percent right and start using it. I think that probably would apply for all of these systems. Rather than take six months and get it 85 percent right. Let the system grown and learn and then feedback to the planning process.

MR. HOLMES: Cisco, before we go to the next one, I would mention I had to walk the talk once myself, so I can relate to your question. I mentioned that I started using Baldrige as a tool and CMMI back in the early 90s. But in the late 90s I was hired as the general manager to be the -- to launch the first internet service for Comcast. So it was basically a startup. We had a very small team. We didn’t get -- we weren’t given a lot of money. We were kind of isolated. It was like an internal skunk works type of thing. And I had to launch it as if I was in a garage in the Silicon Valley. And basically was use all the same principle that we talked about here, since I basically had to make due with just a small, very small team that we had. So I actually can vouch for the fact personally that it worked very well in that kind of environment.

MR. VICENTY: Next question. Yeah.

AUDIENCE MEMBER: Okay. So I have a question regarding how FDA precert is going manage the complexity with what I would call the unhappy pathway (inaudible) as it relates to the SAMD? People asked this morning how -- why don't we just use existing (inaudible)? One of the things that's been obvious today, at least to me, is that when you look at FDA precert (inaudible) you look at software medical device and you look at the existing management frameworks, there is less (inaudible). (Inaudible) with the hardware. If I have a piece of equipment that's three months (inaudible) possibilities. And maybe two of those possibilities are (inaudible). If software is a medical device I may have numerous areas against which I'm designing the happy pathway.

So think of GPS and you're going north on Lakeshore Boulevard in Chicago and says turn right. Are you going to drive into the lake? No. But if you have a patient with PTSD who's (inaudible) or diabetes insulin (inaudible). So my question is how, and it's an important problem for all of us to tackle, how do we

manage to increase our program? The complexity of (inaudible) pathway design and testing to ensure that we've got reasonable -- a reasonable mark from A to Z?

MR. VICENTY: I'm not sure. You know, down the road, I mean that's maybe something Bakul might want to comment on maybe toward the end. But, you know, there is a lot of work that needs to be done within the overall designation to the precert program, right. The application of the excellence principles answer one set of the equation, right. There is only this piece of it that we can address and tackle through here. The other pieces are, you know, something along those lines. How do we get this element of information or how do we get a closed feedback loop, not just for the systems development, but even from an agency standpoint, right, so we could keep tabs on what's happening and we could adjust as we move forward. So I think we are at stage one. You know, how do we start giving everyone a little bit more capacity within regards to this so that we can start tackling some of these other elements that move forward. I don't know if anybody else has got any thoughts on that.

MR. HOLMES: Yeah, I would like to mention the importance of being adaptive and corrective. Whatever framework you use, whatever quality system it just reemphasizes, what you said reemphasizes the need to not only look at how good are you today, because you might be measuring goodness by all the happy pathways that you've taken. But how well positioned are you, first of all, to scan for bad results? Even if they haven't been detected yet, do you detect them?

In the internet world and I'm working with a client right now that has that problem is that they just weren't doing a good enough job on their monitoring side to even know. Because ideally you always want to know before the customer knows and before the patient knows that you're headed down the wrong path. So you have to have systems and processes therefore that will help you identify those things. And then you have to have all the other framework aspects we talked about, the knowledge management to share those processes to prove that they're the right processes, to get better at it.

And then even more so if the system itself is

broken that you have a mechanism to go back, review, respond to that defect and to put corrections in place quickly. And I don't care if you're a Johnson and Johnson that's a global company or you're in a garage, you have to have those kind of processes in place. And if you want me as a regulator to have confidence in that what I'm going to be looking for is that you put those processes in place, that you're aware of it and that you've put it in place and you're checking constantly to be sure that what you put into place is working. And it's that entire corrective system, regardless of your quality management program or model that you put that entire corrective system in place. And that's what I would be looking for.

MR. FISHER: Brian Fisher from Experian Group. So you've done a good job of touching on how this can fit for small and large companies. So to stay in that theme, but as to the inverse, maybe how do you see the models most challenging for small companies? I mean which specific, excuse me, specific areas should the small companies focus in? Or maybe to ask it another way, what advice would you give to a small company who

is trying to implement one of these models to really focus in because it might be their weakness?

MR. VICENTY: Any thoughts?

MR. ROHM: I think, you know, one thing to keep in mind is that it takes time to change hearts and minds. And most folks who are applying these kind of management system models are really trying to change the culture of the organization. You know, that's a two to three-year process, not a two to three month build. So one of the things to keep in mind is that, you know, make sure you're in it for the long term and sell it that way right from the start.

The biggest negatives that we've seen, I'll talk just to the Balance Scorecard, is if there's a leadership change at the top. This program, this framework is driven very much by passionate people. And you want to go as high in the organization as you can to get that passion. Even though it's a relatively short build time the implementation time, the institutionalization time, as I mentioned, is two to three year before it really becomes just the fabric of the way the organization works.

You don't think about I've got to go do Balance Scorecard and then I've got to go do my real job. It becomes the way we work around here. It's a culture change. And I think that's really true for any of these models. You know, don't think of them as just a way to get performance measures or a way to get key projects to work on for Lean or Six Sigma. You know, really think about it as changing the culture of the organization. Because if you're trying to build to excellence or build to high performance that's really what you're doing. You know, and these are tools and there's a lot of them that you can use to help you get there. That's why the answer to one model isn't for everybody, is the right one to pick and choose to get what you want out of it. Engage leadership, that's the key.

MR. ANDERSON: I want to comment on that fact too. Because one of the biggest challenges that organizations face is scaling up, right. And if you haven't done this work on the front end and scaling up happens before you've done it, it's much more expensive and difficult than the organization. If you pick your

structure and build on that it becomes much easier to make it your culture very, very early. So it's really a return on investment proposition for startups. You know, this is something as a leader in my organization starting this little company it gives you the ability to -- it really adds agility from a management perspective.

MS. KAPLAN: Yeah, so I reiterate everything that they have said so far. You need to have executive sponsorship of whatever initiatives you're trying to do. And this might be a little bit more technical, but there are trainings, there are implementation guidelines, there are webinars where other organizations who have implemented CMMI, for example, speak about their experience and what they learned. So there's lots of opportunities that are low cost that a startup could leverage to be able to understand how to implement it early on.

MR. VICENTY: So before we go to the question, just to quickly comment on that. Because it's not, you know, they've got the expertise here from their standpoint and you're doing this. But just from the

limited activities that we've seen and been involved with FDA working with some of these and some of the pilot efforts, what I've seen as a big watch out is don't go and look at the models and use that as your script or playbook for what you're doing. I see that the introduction of that extra complexity is where the biggest struggle happens, especially for a small startup, right. You look at this and you look at the volumes of information. And people try to map to that versus just doing what's right for them and letting that process work itself out from there.

So I mean it goes back to the principles of even simplicity that Dr. Shuren brought up this morning. It's what is the simplest way to get that right level of assurance for yourself, that level of integration and everything that's going on? And then let everything else work out from there really. That's where you start to drive that excellence piece. I think it's similar to what I've heard, at least mentioned here, right. It starts there. Don't start with the model. The model is just, you know, what we can leverage and use. It's what is it that's right for

your situation, your customer base and your organization? And then let that be what kind of blossoms out. I see too much of the flip going the other way around.

MR. FISHER: Yeah, that's a good perspective. Thank you.

MR. VICENTY: Yeah.

MR. FISHER: And thank you all for sharing. I think it'll be a challenge for us as we think about precert that, you're right, excellence is a journey. And even when you mention sort of two to three years, to go through that journey and pull the organization with it's important for us to remember many early stage startups don't even have two to three years of runway. So how do they get to that journey in the timeframe that they have will be a challenge for the program I think. Thank you.

AUDIENCE MEMBER: I just want to know if the could (inaudible) what are the (inaudible) models for the (inaudible) in general?

MR. VICENTY: Third party confor --

MR. HOLMES: Well, I know that, for example,

for Baldrige and EFQM there's independent appraisers or assessors that are used. In a Baldrige world we're called examiners and we get appointed by National Institutes of Standards and Technology and we get trained and we read the applications and we provide a score. And that score is then used in order to judge who wins the award. So if it was going to be -- if the similar program was going to be used there is bodies of people out there who are trained in reading and dissecting the responses that you get back. And I mean I think it's pretty much the same with CMMI and with most of the other models.

MR. ANDERSON: I think what I encourage organizations to do, and I think it would be very beneficial to include it in the model, is requirements for self-assessment. If you want to see an organization change it's not as much the impact from the external accessors, although the value of that external view is very powerful. But that in between there's some type of self-assessment on the appropriate cycle. This is what I see as those organizations that are really committed the more they iterate those

things, first of all, the more it becomes part of their culture. And the second is, is their improvement is much more exponential.

MR. ROHM: We used the Association for Strategic Planning best practice standards to develop this version of the Balance Scorecard. They created a body of knowledge for the profession and have a proctored certification program much like Project Management Institute does with the PMP certification. And part of that body of knowledge is some attribute, best practice attributes for integrated strategic planning and management systems. And that’s how we test whether or not the framework is consistent with that.

And then we’re the only ones who train people to train others. So it’s a review process that we go through before we certify somebody to either do the KPI training or the Balance Scorecard training. We’ve trained about 6,000 folks in 72 countries and have representatives in every continent except South America.

MR. VICENTY: So I think we are done on time.

Just quickly from the FDA standpoint one of the things that we've obviously always left room for is, you know, this can be done through a third party. But I think in the spirit of this is a journey, how do we do that and not turn that into a new compliance bar, right? And that's really part I think part of what we're looking for help on and the development.

I'd like to thank the panelists here and I appreciate it. They'll be available if you guys need to have some questions answered and have more follow, so feel free.

(Applause)

MS. CRUZ: Okay. Thank you everyone. We are nearing the home stretch. We have one last open public comment period of the day. And so, again, I'm going to ask preregistered speakers to come up and give their comments, which would be limited to three to five minutes. First speaker is Carl Washburn from Eli Lilly.

MR. WASHBURN: Carl Washburn from Eli Lilly. I work in device quality. And Eli Lilly is a mature device manufacturer. And I really appreciate

everyone’s participation today (inaudible) and putting it inside the collaborative environment. Thank you for your leadership in making this happen. And so I can see John Murray (inaudible) I’ve learned something insightful and valuable. So a great opportunity for us.

I wanted to share one example of the best practice. And I think this gets to what we’re trying to accomplish with the precertification program. When we were developing (inaudible) the whole concept of device classification didn’t seem to rise to the forefront as it did when we expand our quality management systems and started to develop software. And as we developed software one of the questions came up is, is this classified as a medical device? And if so, what classification? And without a formal procedure in place (inaudible) had conversation after conversation after conversation and then go through the development process (inaudible) change with medical device classification, change (inaudible) classification as well. And so it seemed like we were spending so many cycles on this one concept that it was

hard to do any (inaudible). And so looking at it said there's really got to be a better way.

And so working with device regulatory and device quality came up with a procedure and a process where in conversations and email the development teams would go to, to (inaudible). And they created a discipline assessment form saying what features are you putting into the product? When will they be deployed and in what countries? And or are you going to (inaudible) promotional trainings? And based on that (inaudible) assessment and a signed form on the status of that medical device (inaudible). The form gets reassessed every time that a change comes forward to see if affects the medical device status.

So just looking at the pre and post, huge differences in terms of the clarity of how development teams are organizing. What developments that we are following (inaudible) system. And everyone is really (inaudible) a lot of confusion in the past. So I would encourage us to share any good ideas (inaudible) you have with each other. And we continue to work with you and (inaudible) as a resource (inaudible).

(Applause)

MS. CRUZ: Thank you. The next speaker is Ismael Martin from Psyche. And if Ted Smith could queue up behind him as the following speaker that would be great.

MR. SMITH: Or just Ted Smith?

MS. CRUZ: Or perhaps just Ted Smith.

MR. SMITH: All right. Good afternoon. I'm Ted Smith, I'm Chief Executive Officer of Nuance Systems (inaudible) company. Thank you so much for organizing this event. (Inaudible) and we are (inaudible) optimistic about this process.

That said it would be helpful from our perspective if this emerging framework could be communicated in the context of the existing Legacy framework. And I know some minor attempts have been made on that front. I'll just tell you from our perspective they're not sufficient. And so the presubmission process (inaudible) process, these are existing mechanisms that I think there could be (inaudible). We would appreciate that kind of communication to understand the (inaudible) pathways.

So that’s what we want and that’s on the existing pathways.

And then on the emerging policy (inaudible) some confusion, so, you know, (inaudible), you know, goes directly into some (inaudible). And so while making it impossible to come up with a definitive answer ever, (inaudible) knowledge in the process of developing precert that (inaudible) and to adjust the precert process to reflect current, you know, laws (inaudible).

Then on the sort of just echoing, you know, the part of, you know, this concern of small companies, startups are not well represented in this process. I know it’s difficult to do that. I would argue that it may become important to go back to the small companies to (inaudible) precert that might not be as obvious as one rule applies to everybody.

For example, those of you who are familiar with non-profits the IRS makes it possible for non-profit organizations to fiscally sponsor small emerging non-profits. And they will (inaudible) non-profits really don’t have any (inaudible) process (inaudible)

that status. So could it be possible that a precert could be a (inaudible) sponsorship from a corporation or university to (inaudible) company? In some ways the associates arrangement is like that. So we would like us to make sure that we're not hiding from the startup question, but we're steering into it. Thank you so much.

MS. CRUZ: Thank you.

(Applause)

MS. CRUZ: Danny Bernstein and Suchi Saria. She's not here. Okay. Morgan Reed from Connected Health Initiative. Brian Levine from Close Concerns.

MR. LEVINE: Good late afternoon I suppose. My name is Brian Levine and I'm speaking on behalf of (inaudible) a diabetes information company (inaudible). So (inaudible) software for diabetes and how it has potential algorithms (inaudible) technology and (inaudible) also to facilitate lower barriers for improved life with diabetes, diet, exercise stress and beyond.

So diabetes is a poster child for digital health and (inaudible) select pilot (inaudible)

diabetes. Diabetes is a unique condition that requires constant attention and for medications (inaudible) most dangerous drug in the world in insulin. (Inaudible) people with diabetes (inaudible) condition over 600 times per day. (Inaudible) .007 percent that (inaudible). So and that's out 219,000 times that (inaudible) diabetes (inaudible) only 1500 times.

(Inaudible) support, particularly for (inaudible) will be critical. (Inaudible) in those area (inaudible) in the past few years, but they will accelerate massively moving forward. Having a system that encourages (inaudible) while preserving safety and surveillance (inaudible) huge for many factors and patients alike. The problem with diabetes apps (inaudible) still sort of a (inaudible). In that neighborhood of 46,000 analyzed the list (inaudible) and the conclusion that only 31 have a risk, or 31 had a risk of inappropriate dosing of one of the world's most dangerous drugs. So there is no (inaudible).

I would strongly encourage that from a precertification stand that providers and patients (inaudible) safe and effective. That does have

(inaudible) that vision of excellence or should that be different (inaudible)? The (inaudible) you have silver, gold (inaudible) process. Then provide a (inaudible) of each of the excellence principles. (Inaudible) and also (inaudible).

The other main recommendation I have would be (inaudible). When we're talking about (inaudible). But people are spending more time (inaudible) and less time (inaudible). (Inaudible) 300 times a day to go to 600 that would be a hugely successful product even (inaudible). CDRH has been at the forefront of (inaudible) and we would love to see that focus (inaudible) with the precert program.

(Inaudible) thank you for sharing, Bakul and (inaudible) your dedication (inaudible) access (inaudible) as quickly and safely as possible.

(Applause)

MS. CRUZ: Thank you. And our last speaker will be Jen Hornjeff from Savvy Cooperative.

MS. HORNJEFF: Hi there. Jen Hornjeff with Savvy Cooperative. And we are a patient owned co-op that really devotes our efforts to make sure that the

patient voice is heard when we think about creating this new technologies. And I really appreciated what I heard today on the panels and the comments from the audience members about making sure that we're including all those stakeholders.

And I think traditionally when we've thought about the healthcare system we've thought about payers and providers and many others in the industry, but we forgot about the end user. And that's what is really encouraging to me today is to hear about those that are actually using these products and making sure that they're accessible. And that when they're created we can understand what those sort of pain points are with the patients in mind.

So, again, I will keep this short. I know we are running towards the end of the day. But I want to thank the FDA for their committed work towards working with patients to make sure their voices are heard and to get all the stakeholders together in the room so we can co-create. And I really look forward to tomorrow's workshop and doing that. Thank you.

MS. CRUZ: Thank you so much.

(Applause)

MS. CRUZ: Okay. We very much appreciate your attention and participation today. Just to round things up I'm going to turn things back over to Bakul.

MR. PATEL: Thank you, Marisa. I just wanted to offer just in the last people who had signed up for commenting, again, if you want to make some comments this might be a good opportunity to stand up and make your comments and reflect on the day. '

But I want to close out the day with we started from the top with Dr. Shuren talking about how we are trying to push and lean forward and trying to make products available to patients as fast as we can that are safe and effective without actually compromising the bar of safety and effectiveness.

We also talked about how the program is evolving over time. And I actually applaud all of you just sort of in helping us build it. And I loved the engagement that you sort of brought to the table today. Love to continue that going forward tomorrow.

We are actually going to have breakout sessions diving deeper into those discussions and

trying to find out the balanced between, you know, I heard many times today don't forget the small industry and the small startups. That's exactly what we want to do is identify how do you tie -- how do we make sure that the small folks and the people with ten, fifteen, five-person organizations who have the right thinking, who have the right infrastructure in place can actually meet the excellence bars that we're trying to meet.

At the same time making sure that the things that we expect, clinical evidence and making sure those right rigors are in place, etcetera, are still there. We want safe innovation to go forward, not just innovation. So making sure that happens and making -- helping us in being informed with those ideas and traits and sort of mechanism that are put forward is really, really important for us.

So thank you and give yourself a round of applause for actually participating really actively today. Thank you.

(Applause)

MR. PATEL: We're going to call it a day today. And then right back here at 8:30 tomorrow?

Yes, 8:30 tomorrow. See you tomorrow. Quick announcement to moderators who are moderating.

(At 4:54 p.m., session ended for the day.)

CERTIFICATE OF NOTARY PUBLIC

I, Casey Smith, the officer before whom the foregoing proceeding was taken, do hereby certify that the proceedings were recorded by me and thereafter reduced to typewriting under my direction; that said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

CASEY SMITH

Notary Public in and for the

State of Maryland

CERTIFICATE OF TRANSCRIBER

I, Wendy Sardina, do hereby certify that this transcript was prepared from audio to the best of my ability.

I am neither counsel for, related to, nor employed by any of the parties to this action, nor financially or otherwise interested in the outcome of this action.

February 13, 2018

DATE WENDY SARDINA