VOLUNTARY MEDICAL DEVICE MANUFACTURING
AND PRODUCT QUALITY PROGRAM
MEETING
Tuesday, October 10, 2017
8:09 a.m.

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Reported by: Michael Farkas
Capital Reporting Company

A P P E A R A N C E S

Jeffrey Shuren, FDA/CDRH
Stephanie Christopher, MDIC
George Zack, Two Harbors Consulting, LLC
Kimberly Kaplan, CMMI Institute
Robin Newman, FDA, CDRH
Captain Sean Boyd, FDA, CDRH
Cisco Vincenty, FDA, CDRH
Nathan Tenzer, Edwards Lifesciences
Luann Pendy, Medtronic
Frank Meledandri, Zoll LifeVest
Cynthia Grossman, Faster Cures
Hudson Garrett
Joe Friedrich
Cynthia Grossman
Al Crouse
Adrian Furey
George Zack
Pat Baird
Cindy Winfrey
Emily Miner

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

George Serafin
Erin Keith
Joan Richards
Jack Mitchell
Gene Parunak
Mark Rutkiewicz
Andrew Mazurkiewicz
Sandy Charlton
Todd Snell
Dawn Stenstrom
Aaron Kehrer

I N D E X

I N D E X (continued)

P R O C E E D I N G S

MR. BOYD: Good morning, everybody. Take your seats. We're going to get started. My name is Captain Sean Boyd. I am the deputy director for regulatory affairs in CDRH's Office of Compliance.

And welcome to our public workshop on Voluntary Medical Device Manufacturing and Product Quality Program. Today's -- or today's agenda is full of a lot of exciting talks that we hope you're going to get out -- a lot out of.

This morning we'll hear from our leader of CDRH Dr. Jeff Shuren as well as some leadership within both MDIC and the community to talk about elements of the voluntary program.

We'll also begin hearing from various stakeholders on the value proposition for this program and case for quality in general.

Before we break for lunch one of the things that I need to ask that you do is if you could go to Sodexo and place your lunch order by 10:45, which is the time we've scheduled to have the morning break conclude. That will ensure that everybody gets the

meal that they've requested.

This afternoon we will continue with another session on the value proposition as well as hear a couple of panel discussions regarding health outcomes to patients, value to industry, and benefits to healthcare, as well as identifying risks and mitigation strategies before we break again and have an open public session for presentations by workshop participants.

Currently there are about ten days left in the public docket during which you can provide your comments and input on the proposed voluntary program. We also intend to extend the open public comment period another 45 days and that will publish in the next couple of weeks or so.

You also have the ability of providing input and feedback on this program at the email address caseforquality@fda.hhs.gov.

And lastly, there is public internet access in this building. The network is identified as FDA-public and the password is "publicaccess", all lower case, no space between. And we'll provide that up on

a slide during the break, as well.

So with that it's my pleasure to introduce Dr. Jeffrey Shuren who's the director of the Center for Devices and Radiological Health for some opening remarks.

MR. SHUREN: Thank you, Sean. Good morning, everyone. Welcome to our meeting on the Case for Quality Voluntary Pilot Program. I'm just going to take a few minutes and give a little bit of background about Case for Quality, how we got there, and how we got to today.

And for us everything starts with our vision. When patients in the US have access to high-quality, safe and effective medical devices the public health importance first in the world.

And normally when we talk about that vision there's a big emphasis on safety and effectiveness, we want technology to benefit patients. And we talk about first in the world not as a competition between countries, but as a good measure of timely patient access because we know even if a technology is good it's not going to be of great value to patients if

they don't have timely access.

But I want to highlight two other aspects of our vision. To begin with, the very first word in our vision is intentionally patients because patients are at the core of our mission. To improve the health and the quality of life of patients is job number one for CDRH.

And secondly, high quality. So we don't just talk about devices as being safe and effective, but high quality, safe and effective medical devices. Because we can review evidence and determine that based upon that we think the technology will be safe and effective.

But, again, it's not really safe and effective for patients unless it's of high quality. And the manufacturer can consistently and reliably make a high-quality product. And if not, then we are putting patients at risk and we are jeopardizing our core mission of patient's first and that's why this is so important.

So Case for Quality started back in 2010. It all came around a case of a company who had three

recalls in the space of two weeks. That involved three different products at three different facilities with three different problems in their quality system. And so we had a dialogue, talked with the team about it, what's going on here?

It was, well, a problem here, problem there. What really came out of it is the real problem was at the corporate level. That quality didn't seem to be of great value maybe to the company and that the issues we were seeing with the quality systems were more symptoms rather than the underlying condition we needed to address.

So we started to pull data. We did a deep dive into our prior experience with inspections and warning letters. And what we found is we would go out, we'd do inspections, we'd look at a particular subsector in the industry, do a deep dive, and we were finding the same kind of problems quality system and we sent out a bunch of warning letters.

And things get a little bit better, we look at another subsector, same issues, send out warning letters, then we come back to the prior subsectors and

the issues would crop up again. So we were essentially playing a game of whack-a-mole.

And that wasn't to say that what we were doing wasn't of value, but we clearly were not being successful in assuring that the products were of high quality. In fact, it's becoming very clear that while compliance may be important, compliance is not synonymous with quality.

So we contracted with McKenzie and Company to do an assessment of is there value to investing in quality. Essentially is there a business case for quality?

And what they found, a report they put out in 2011, is that for those companies who did invest in quality kind of from the corporate level on down throughout the organization they were seeing a return on investment, reduction in adverse events that was translating into not having to chase their tail on problems and less issues with loss of market share and consumer confidence. So there was value to the organization, value to patients, value to the company in doing so.

They also identified several barriers. So one was the FDA itself that our focus on compliance with our requirements created disincentives for manufacturers to innovate around product and manufacturing quality.

And in addition because of our big focus on compliance with the regulations companies were saying, okay, then if that's what matters that's what we'll focus on. Just make sure we could check the box and we can pass the FDA inspection.

But, again, complying with FDA requirements they're important. I'm not telling you don't do that. However, that doesn't assure that, again, we have manufacturing and product quality.

The second is a lack of transparency in the marketplace. A lack of comparative data to know who's doing a good job and who's not. And there's a chance for companies to benchmark themselves against one another something that we see in other industries.

You know, in the automotive industry starting way back in the 18 -- in the 1880s, yeah, sorry about that, Ford -- no, the 1980s you started to

see competition around safety and quality and that has only accelerated with time. And, of course, that exists in other industries like the aerospace.

But it wasn't a case here in device -- in the device industry. And so we started look at then what should we be doing? And there was clearly a failure in the marketplace. A lack of transparency and good data around what was going on.

And the solution to us wasn't simply to act as a regulator, but what could we do to sort of drive a shift from a compliance mindset to a quality mindset? That we have a much more flexible paradigm that fosters a competitive marketplace around quality much like we see in other industries in the U.S. And that led to the kickoff of the Case for Quality.

Now in 2013 we worked with the medical device innovation consortium, public, private and partnership for advancing regulatory science in medical devices on creating a collaborative forum for us, industry, and other members in the medical device ecosystem to try to create that landscape and what kind of a shift in paradigm did we need and to do so

through engagement, through collaboration in a very trusted environment.

Now in 2016 we ran a pilot with three companies to assess the value of using the capability and maturity model integration appraisal process. And out of that feedback that we received which was generally positive about the potential value of using that approach has led to today as we sort of kick up -- kickoff our developing and then launching a vio- -- violent -- it is early in the morning. Sorry about this and I missed coffee. But, yes, a violent pilot program.

So folks expect a lot of bloodshed. It'll be tawdry. But please wait for the closing credits where you'll see scenes from the next movie in the franchise. You do not want to leave early.

So out of that we sort of kicked off this program, this pilot program. And what we're applying are several principles. So first off that we would be using a maturity model appraisal as opposed to a compliance model first off.

Secondly, that we would be leveraging third

parties. It's not something that the FDA can be out there and doing the assessments on, but how do we set up for a third-party model where we have trust in the work of the third parties and then the agency can go ahead and leverage that to identify objective metrics.

And it's going to be important that those metrics are a value to purchasers and users because they'd be looking at the data as to is this meaningful to them and can they make better informed decisions.

When I buy a car I go ahead and I look at the ratings. I look at what -- how they measured up and I make a decision on what to buy based upon that. If there was a measure for color, that would be a lot better for my wife, but I do work off of safety and quality.

Then it's to go ahead and look at then what's the impact at FDA? What changes do we at CDRH at our Office of Regulatory Affairs need to make in order to sort of encourage this better focus on product and manufacturing quality and organizational performance?

You know, that may include revisiting the

QSIP. Are we really focused on the right things when we go out and inspect? And if we're going to leverage any kind of maturity model, then what impact does that have for how we can better use our resources?

When and where do we really need to do an inspection or otherwise could forego it? What are the opportunities to maybe forego preapproval inspections and conduct those in the post-market settings? Are there opportunities to provide more leeway around 30-day notices?

And then to go ahead and evaluate the scalability of the program. So we will go ahead based upon all the input we receive to announce the pilot in December and ultimately launch it early next year.

So I have a call to you, a call to action. If we're going to be successful, it's absolutely critical that all of you engage. We need your feedback. And there will be many opportunities to do so now and in the coming months.

Most important is to participate. Remember there was a slogan for a lottery a while back you have to be in it to win it. So it's the same thing here.

You've got to participate if you really want to see value come out of this effort.

Thank you again for coming and thank you in advance for engagement and participation. I'll turn it back over to Sean.

MR. VINCENTY: Good morning and welcome. My name's Cisco Vincenty and I'm actually in the Office of Compliance. And I've been working on the Case for Quality more dedicated for the last few months trying to make sure we're moving things along.

And in the spirit of good quality practices and principles, right, I arrived just in time. You know, we really, you know, trying to lean things out. No time for that pesky preparation getting things ready, getting comfortable.

Luckily Sean stepped up and covered what was going on here. But we're going to start the rest of the program, get things rolling. And what I'm going to introduce right now is I'm going to introduce Stephanie Christopher who is the program manager for our Case for Quality with MDIC.

She's going to give a little bit of

background of MDIC, our engagement, our involvement, and the real benefits that we've gotten out of that venue.

MS. CHRISTOPHER: Well, good morning. It's my pleasure to be here today to represent MDIC and tell you a little bit about the history of Case for Quality and MDIC's involvement and how all of you can engage in the Case for Quality.

The Case for Quality isn't just a project. I think it's really become more of a movement and MDIC's been privileged to be a part of that. As the only public/private partnership focused exclusively on regulatory science for medication devices it's been a great opportunity for us to engage with this community and a great opportunity for me, personally, to work on this project and to get to know and get to work with many of you.

My background is more on the patient engagement side and I also work on MDIC's patient engagement initiative. But make no mistake, the work that you all are doing here today has a direct impact on the lives of patients and that's why I know the

folks at MDIC are always so excited to work on this project and continue to engage with all of you.

For those of you that aren't familiar, a little bit about MDIC. We're a 501(c)(3) non-profit organization. We're the first -- as I mentioned, the first ever public/private partnership created with the sole objective of advancing regulatory science of medical devices for patient benefit.

We have 62 participating members including industry, FDA, CMS, non-profits, and other patient groups. We're actually founded in Minnesota in Medical Alley. I know many of you are -- came today from Minnesota and are active participants in that community, as well.

Some of our projects include work to advance U.S. based early feasibility studies, guidelines on the use of virtual patients to reduce the size of clinical trials, our work in advancing patient preference research for regulatory submissions, and framework for the use of surrogate samples and IBD test development

Last year in 2016 we were -- MDIC was

awarded a contract to develop the coordinating center for the National Evaluation System for Health Technology or NEST.

So how does MDIC work? What exactly do we do? Well, one place -- one thing that we do is we create a forum for collaboration and dialogue. I like to say that MDIC is a safe place for industry and FDA to work together on challenges facing our industry.

Many of you have been to our forums or our events and these are intended to be interactive opportunities to really work -- wrestle with the problems facing our industry and to work together on solutions that will benefit everyone. Ultimately we all have the same goal which is to advance getting those medical devices into the hands of the patients that need them.

We make strategic investments in regulatory inves- -- in regulatory science. And these include things like improving efficiency and cost effectiveness of device development, focusing on med needs, and improving the innovation cycle time.

In particular, we work on the development of

tools to drive innovation particularly for the benefit of this group and that quality and patient safety avenue.

CDRH has given a terrific history of the Case for Quality, but I want to elaborate on a few things. Now I wasn't at the launch of the Case for Quality but I'd like to think it looks something like this. It was -- there was a lot of people in a government room and there was things, some papers signed.

But really CDRH launched the Case for Quality again because they recognized that compliance and quality didn't -- compliance didn't necessarily lead to quality and there was a need and a desire to really drive quality in our industry.

MDIC was awarded a contract to -- in 2014 to really help to advance the Case for Quality and we did that in a couple of key ways. We convened this series of forums. These were meetings where we were able to bring together folks from the industry, bring together different quality experts, and folks from the FDA to really have a dialogue about what was needed to drive

that qual- -- that vision of a culture of quality within -- within the industry, what tools do we need to develop, what tools could we build on that already existed but just needed to be further refined for use on a day-to-day basis.

From 2014 to 2016 the MDIC focused on four different initiatives within the Case for Quality. The first was development of a maturity model. And you'll be hearing more about that maturity model today. But how we could take a model -- an existing model and use that to be able to demonstrate quality within medical device manufacturers.

We also had a project on metrics. How do we measure quality? How do you tell if some -- if there is quality practices going on within an organization?

In addition we had a project on competencies. How do we -- what are some of the key things that you need to know about quality? How can we educate folks within the industry about quality practices? And finally we had a project on analytics, looking at how we can compare quality across device types.

In 2017 we focused not so much on these different project activities, but how we can put all of these pieces together and really launch something that CDRH can use for their quality projects. So it was taking those different pieces that we've worked on over the years and fitting them together into that culture of quality.

The vision for the Case for Quality was and continues to be to elevate the focus of all medical device stakeholders from a baseline regulatory compliance to sustained predictive practices that advance medical device quality and safety to achieve patient outcomes.

The goals have been to develop new tools, methods, and metrics for innovators, manufacturers, regulators, and providers that improve product quality and patient experience.

As I said, this year we've had a couple of focus areas. One has been are ongoing Case for Quality forum that encourages stakeholders to participate in discussion around opportunities for improving device quality around the industry.

Our final forum for 2017 takes place next month, November 15th. And I have -- I'll have the link up there for all of you. But I encourage you, that's a great opportunity for you to continue, you know, engagement with the Case for Quality and continue to learn and interact with a lot of the folks you'll hear from today.

Our maturity model program focused on developing a means for using an independent assessment of quality maturity at a device manufacturer. We built on what we learned from the pilot this year and continue to further refine that maturity model to make sure we could develop something that would for -- that would work for industry, what would work for FDA, and that would be able to be implementable and scalable in the long term.

Our product quality outcomes analytics groups continues to work to create a program aimed at creating a standard, independent, and reliable source of information on device quality and really has focused this year on the use of registries and hospitals. And has really made some tremendous

progress in advancing how we use information from hospitals and really being able to use that to glean quality data that can be usable for patients and providers looking to make decisions.

And finally, we're a resource to provide information to CDRH. We're a place for you -- for industry to be able to provide feedback on the program and for us to be able to help continue this program over time.

You'll hear more on the maturity model later today, but just to give you a brief overview the intent of this was to develop a voluntary program which leverages CMMI as the standard maturity model by which industry may measure their capability to produce high-quality devices.

And I've had an opportunity to sit in on many of the working sessions for these and I've really taken these are learning opportunities because this was not my background. But really the level of commitment to this initiative has been tremendous and they've really made sure to apply an existing model and really make sure it works for the specific needs

of the medical devices industry.

CMMI was selected for the development of a quality maturity model for the medical devices industry based on a couple of factors. It was globally recognized across multiple industries. It's been used in a lot of different places including in the medical devices industry.

It's a well-established 20-plus year program with demonstrated success. It's governed and maintained by an independent authority that also performs the assessment so this is that third party that Dr. Shuren was talking about that they're going to be the ones doing the assessments. And they really have the background and the understanding of what quality should look like within these organizations.

It's a well-defined program in terms of people, processes, and technologies and it has flexibility across companies of different sizes. We realize medical device companies are not all the same. They're different sizes, they produce different things. Some of them produce multiple things in the same facility and it needs -- we needed a model that

could be flexible enough to handle that.

And finally there was ability to update with regul- -- as regulatory changes come out. The model was flexible enough to be able to handle those.

I want to make sure to mention our product quality outcomes analytics project. As a patient myself and the adult child of a patient with -- a parent with healthcare issues this project has actually become near and dear to me.

Because, as Dr. Shuren said, if you're trying to make a medical decision or help your parents make a medical decision it's really hard to be able to look at devices across the board and be able to assess the quality of those.

What the analytics group is seeking to do is to use the tremendous amount of data that's out there about device pra- -- device use and to be able to present that information in a way so that hospitals and physicians and patients can make decisions based on quality.

The group had come up with seven different measures of -- or factors of quality that they

highlight. And those safety, efficacy, reliability, patient perspective, usability, compatibility, and availability.

So, as I mentioned, I want to encourage you to get involved and stay involved in the Case for Quality. There are a couple of opportunities including our upcoming forum on November 15th.

If you're interested in enrolling in the pilot, you can also learn more on MDIC's Case for Quality website. And we even have updated our frequently asked questions which I'm really excited for you all to take a look at.

So I guess I can take a few questions if there are questions, otherwise I will -- or you can save the tough questions for…

FEMALE SPEAKER: Good morning. Just a quick look at your list of the seven points right there made me think about interoperability and maybe that's addressed under one of those. I wasn't really sure.

As I think about, you know, the internal things and how devices are becoming more interactive with each other --

MS. CHRISTOPHER: Uh-huh.

FEMALE SPEAKER: -- I'm thinking of my husband and his glucose monitoring and, you know, his pump and all that kind of stuff. I'm just interested in how that will be addressed the internet of things and devices.

MS. CHRISTOPHER: Absolutely I think interoperability is an important thing to think about in device quality and across all devices. And I think it really -- within the, again, good scheme of how we set it up here I think it really falls more under the compatibility is kind of the category that they -- that they fit that in under. But it's -- it is an important area to consider for sure.

All right.

MR. VINCENTY: No more questions. So, Stephanie, just out of, you know, you mentioned from your standpoint, right --

MS. CHRISTOPHER: Uh-huh.

MR. VINCENTY: -- that you are always learning.

MS. CHRISTOPHER: Uh-huh.

MR. VINCENTY: It's not your background. Technically it is my background, I'm always learning when we get into some of these forums. So the engagement that we get through these -- you know, these opportunities, the forums that are held bring other people together it really helps to get to I think something that Dr. Shuren alluded to earlier with the root cause, right.

MS. CHRISTOPHER: Uh-huh.

MR. VINCENTY: What are the right things to be addressing --

MS. CHRISTOPHER: Uh-huh.

MR. VINCENTY: -- as we're moving forward. So as you're progressing, I mean, do you think it -- what are the, I guess, key challenges MDIC has for sustainability to make sure this keeps on going and more I guess in that same being able to continue that kind of engagement?

MS. CHRISTOPHER: Uh-huh. I think one thing that we're really looking to right now and one of the topics of the forum in November 15 -- on November 15th is really envisioning what Case for Quality is going

to look like in the long term. I think for so long MDIC and all of us have thought about Case for Quality as a project or as this discrete thing. But really what we're talking about is what this is going to look like in the long term and how we make it a sustained movement and how we keep it from becoming another check-the-box activity.

I think that's going to be the biggest challenge is that, okay, so we're moving from, you know, I mean, we still have -- you still have those compliance requirements, like you still have to be compliant.

But as we move to this quality system how do we make sure to keep that emphasis on quality and not on the, oh, this is another burden or another thing I need to complete in order to, you know, get my product to market. So I think that's going to be the -- one of the continued challenges is to think -- to kind of keep that mindset of quality and to not create something that just creates another check box activity.

MALE SPEAKER: Hi. You use the term

"patient report data".

MS. CHRISTOPHER: Uh-huh.

MALE SPEAKER: I would imagine that most patients who are having a procedure or even having home healthcare do not have the wherewithal to report on the devices or their therapy they've been receiving.

So how and where are we going to gather this data?

MS. CHRISTOPHER: That's an interesting question and it's going to depend on a lot of different things. I think one of the things that I believe that if we're going to ask patients to report data on their device we have to do it in a way that seamlessly fits into their lives and reduces the burden on them as much as possible.

And whether that be through, you know -- so if any of you have ever -- so my prior background prior to coming to MDIC I was a research coordinator. And if you've ever had to do any sort of study where people have to keep a journal you know people are sitting in the parking lot before they're coming in

for their visit updating their journal, you know, the data. You're not -- what you're getting is not necessarily high quality.

But I think use of technology, you know, being able to integrate more seamlessly into their lives whether it be reminders on their phones or other -- other means of prompting them to record data in a way that does -- is least obtrusive to their day-to-day life is going to improve the quality of the data that we can receive.

All right. I've answered all questions I guess. All right.

MR. VINCENTY: So one thing to just keep in perspective and following up on that question regarding the, you know, the patient provided data and how do we start moving there.

I think one of the fundamental principles that we're really trying to achieve with the Case for Quality is to start shifting our engagement to be able to provide more capacity across not just us, but even through the industry.

How do we start thinking about those

problems and start tackling those better? Start moving the focus away and look for other ways to really achieve the same assurance maybe a little faster, but start to enable that movement so that we can get there. It's just starting to take some steps is what we're really looking to get underway here.

So I'm going to introduce next, you know, CMMI, the institute itself, and Dr. Shuren mentioned it, they've been a phenomenal partner in really working with us, really working to develop a way to go in and look at where the manufacturers are in their maturity journal, but not turn this into something that becomes the next compliance tool.

So I'm going to introduce right now it's George Zack and Kimberly Kaplan. They are -- you know, George Zack is the principal co-founder for Two Harbors Consulting and Kimberly Kaplan is our program manager. She's a program operations manager for the Case for Quality efforts within the CMMI Institute.

And they're probably going to start going through the process of what we're looking to do, how we're doing it, what we're actually looking to

collect, what we see. You know, a lot of the big questions I think a lot of the manufacturers have here when they think about what it is that we're going to be leveraging through this third-party activity.

So with that, I don't know if you're coming up together or one at a time.

MS. KAPLAN: Okay. Great. All right. Good morning, everyone. Thanks. As Cisco said, I'm Kim Kaplan. I'm the program operations manager for this pilot at the CMMI Institute. I've been deeply involved in the development of this program over the last year.

Until recently I was functioning as the project manager in collaboration with MDIC's maturity model working groups which include members, of course, from MDIC, industry, FDA, institute, and other professionals. So I'm excited to be here with you all today to share what we've been able to do after a year of joint effort.

MR. ZACK: Thanks, Kim. Thanks everybody for coming today. I am George Zack. I'm with Two Harbors Consulting. My firm has been involved with

the development of this pilot program in collaboration with the institute, the agency, MDIC, medical device organizations, and lead appraisers.

We're really excited about what this pilot program holds. My firm has been using the CMMI framework as a method by which organizations can benchmark their processes and their capabilities and then further improve those in a variety of areas. Areas such as customer satisfaction, time to market, and, of course, quality.

So we're going to get into it now, right. We're going to talk to you a little bit about what CMMI is. We're going to do an overview of the program. And with that we will drill into what the CMMI Institute's PMO Office, how they will support the program as it's been defined here. And then we'll have some time for Q and A.

With the Q and A there's a few key questions that we've already heard prior to this. We're going to try to answer some of those before we jump into an open microphone Q and A.

MS. KAPLAN: All right. So what is CMMI?

As you heard earlier, CMMI stands for Capability Maturity Model Integration. This has been around since the 1980s and was used as the golden standard for organizations to prove that they are capable business partners.

It's -- the model, itself, is industry agnostic and can be applied to any level or section of an organization. For over 25 years our lead appraisers have helped thousands of organizations across the world to adopt CMMI so that they can understand and solve their performance gaps.

As you can see the CMMI framework has been im- -- has been utilized by organizations in a wide variety of industries. And as the global leader in the advancement of best practices in people, process, and technology the CMMI Institute has been happy to lend a hand in modifying our standard model to maximize its purpose for this medical device pilot program.

MR. ZACK: Okay. So as Kim said, the CMMI model has been around for decades. Over 2,000 appraisals were performed last year. But in this case

since we're dealing with interactions between medical device organizations and the FDA we wanted to make sure that we represented the needs of all the stakeholders in defining what those handoffs look like.

So we -- the folks that have been involved, the companies that have been involved are organizations that have been involved with MDIC and participated. I'd like to thank all the organizations that are listed up here. These are the folks that actually week in and week out were getting on the calls, putting pen to paper, helping us make decisions as to what's going to be in the best interest in defining this particular pilot program, what do those interactions looks like.

This is a pilot. So what we have defined, what we're going to share with you today is an outcome from the learnings that we gathered from executing this against the three early adopter pilots that we performed last year.

And as we continue to move forward and execute more of these particular appraisals in this

particular market we will continue to learn from that and adapt the program so that it is even more efficient and effective.

As you can see here we've -- we have representation from the agency, from the Institute, from professional services firms, and most importantly the medical device organizations that would be undergoing appraisals.

So thus far the -- this has essentially been our governing structure and this is also the governing structure that we're expecting to leverage going forward through the pilot program.

We have a pilot steering team that, of course, provides our leadership direction, making sure that we're aligned with the goals for the Case for Quality of course is the agency. We'll talk a little bit about -- in the upcoming slides we'll talk a little bit about where the agency is providing regulatory modifications, verifying participants, having visibility into appraisal results.

There's MDIC which has been coordinating our working groups specifically in the areas of

enrollment, appraisal, measurement, and the overall program.

There's also you'll see reference to us here speaking about the appraisers. These are the -- the experts in the model that actually execute the appraisers, provide those findings back to the participants, and coach those organizations through increasing their capabilities.

Of course there's the participating device manufacturers and organizations. They're the groups that are actually receiving the appraisal. They're the ones that are going to be actually driving those particular improvements and demonstrating that progress.

And then the big block at the bottom one of the things that I've been working on with Kim and the other stakeholders in the working groups is the CMMI PMO. This is the group that's essentially I call them air traffic control. They're the ones that are pulling together the appraised organization, the appraisers, the FDA, the various stakeholders to execute the appraisals, to track the data, to do

analysis on that data, to continue to drive the particular processes.

All right. So this is a very busy slide, but essentially I'm going to spend a few minutes on talking about this slide going from the upper -- the upper left in a clockwise fashion all the way down to the lower left.

You'll sometimes hear us refer to this as the MDDA program or the MDDAP, it's just another word that's been used in this program, the Medical Device Discovery Appraisal Program.

So starting in the upper left we have an organ- -- well, we'll start with an organization enrolls. This is where the medical device organization, that manufacturer, any medical device manufacturer that is established with the FDA either domestic or international can actually enroll into the particular program.

With that the PMO, the CMMI PMO, so that blue, orange, green ball that you see there represents the CMMI PMO. They start enrollment processing. So, of course, there's some initial checking do we have

where this organization's from, do they have an establishment registration, have they entered the right information, do we have a point of contact for that enrollment. And they pass that information over to the FDA.

At this point the FDA would approve the enrollee assuming that they have a good compliance profile. And you'll hear a little bit more about what that is later on from -- from Sean Boyd later on this morning.

Based upon that compliance profile once they get approved one of the regulatory modifications that the FDA would be providing is that there would be an elimination of the routine inspection for that particular facility.

All that is supposed to happen within about a week from enrollment to approval. Now our experience has been there's usually quite a bit of conversations. We've already had some organizations enroll. But before that there's usually quite a bit of conversation with that organization to further understand the program. With our large medical device

manufacturers there's usually some conversation internally as to where they want to direct this program if they have multiple facilities.

Once that approval is started within 30 days of enrollment this is where we start conversations between that organization, the CMMI PMO, the FDA, and an appraisal team to start to schedule and scope the appraisal itself.

So these are the detailed conversations that are going to occur. So as you may imagine a medical device manufacturer that is manufacturing one medical device this may be a very focused conversation that can occur very quickly.

We manufacture one device or we're a contract manufacturer at this particular location and we can very quickly land on a scope conversation with that particular organization.

Alternatively, with some of the organizations that we've started with already they may have in excess of 50 devices that they're manufacturing at that location. And so with that we have to consider those within the scoping of that

organization. Are those all of a similar class one, two, or three? Are those all catheters? Is there similarities in the process manufacturing that's considered with that particular location?

We're not going to necessarily look at every one of those particular devices that are there, but instead look at families of devices in accordance with a sampling plan that's already been defined by the CMMI methodology description.

We look to have that conversation within 30 days. That goes back and forth a little bit because in addition to the scoping there's also the scheduling conversation that needs to occur. And this has to be cognizant of the availability of the appraisers, but also when the device organization can actually entertain an appraisal activity.

Within 90 days of the enrollment and this is -- this is a goal statement at this point within 90 days. There may be some variability there. But within 90 days we're looking to actually perform the appraisal on site.

So with that -- and we'll talk a little bit

about what that appraisal looks like here in a couple slides and some of the inputs and outputs. You see there's a picture there of a couple of data tools that we'll be leveraging one of which is related to CMMI appraisal results. That's the one that is the red, green, yellow on the left of the slide or the box there and then also a data tool for metrics specific to that organization.

That appraisal is performed. Typically we're looking at appraisal activities being on the context about a week. It could be shorter, could be longer depending upon how that was scoped out.

So this is your -- basically this is your benchmark. This is your initial health check against the CMMI frame work. Where do you stand against the particular process areas within the CMMI framework? And we'll talk a little bit about what those look like.

Once that appraisal occurs you will have findings as to how your organization is performing against the CMMI framework with all the details as to what the appraisal team saw and any areas. There's

strengths, notes, or weaknesses against the CMMI framework.

That data then gets passed back to the CMMI PMO. So we are in the -- I'll call it the 3 o'clock block way over there on the right. The CMMI PMO when they collect that data they're going to be collecting it from many device organizations.

And so by looking at that data across each of those organizations obviously over some period of time and over some number of appraisals they can start to look at trends. Are we seeing that all device organizations in a particular process area against specific practices that they're doing well or that there is some opportunity for improvement in all of those particular areas?

Moving to the lower-right box they then pass -- and we'll talk a little bit more about this because you see there's a -- that heat map has a big black box there. They did pass some of that data over to the FDA. And this is where the FDA gets visibility into that organization, how they're performing against the CMMI model, and also how that organization is

measuring their own objectives and their quality system.

So we basically so far have covered there's enrollment, there's verification of enrollment, there's a scheduling and planning of the appraisal, there's the appraisal executed where you get your initial baseline results, there's some collection of that data, and then there's some passing of that data in part back to the FDA so that they have visibility into the program.

At that point you see as we move over now to the 6 o'clock portion of the slide, the bottom part of the slide you'll see that the manufacturing submission benefits begin. And we'll talk a little bit later on as to what some of those manufacturing benefits are.

On a regular basis somewhere between 90 and 180 days there is what we're calling a checkpoint. This is a regular check in with the organization to encourage their involvement, to see how they're tracking on the issues that may have been identified as a part of the CMMI appraisal, and to see if their involvement -- their leveraging of the CMMI framework

is also moving their quality system metrics.

This could be -- the minimum standard that we're setting for this right now is six months. We'll talk a little bit about this. And this is a remote activity. We'll talk a little bit more about this in a future slide. But it could be more frequent depending upon the needs of the organization.

The PMO will continue to collect this data back from these checkpoints, continue in that trending for reporting back to the participants in the program in an anonymous fashion. So if you're an organization that's participating in this, you'll have some visibility into how the body of all the organizations that are participating, where we're seeing strengths and weaknesses so that you can further engage in that conversation as to what's appropriate to move the industry.

So there will be an annual appraisal. You see there next to annual appraisal it says: "Participants can expand appraisal scope for their needs."

We have identified 11 practice areas within

the CMMI model that you'll see here in a moment specific to this particular program. But if an organization is interested in many of the other practice areas that are in the model they can scope those up to further add value to their appraisal.

And, of course, again, as I said, this is a pilot. So all the participants, the appraisers, the medical device organizations that are being appraised, the FDA, we're collecting regular feedback from those organizations to further improve this program.

MS. KAPLAN: All right. That was a lot of information. But, as you saw, the CMMI Institute PMO has a lot of touch points so how do we make sure that operations run smoothly?

Well, we've created an operations playbook for all of the Institute employees that will be part of this PMO ranging from our customer support specialists who will handle enrollment and any incoming questions to our quality analysts that will look at that appraisal detail, make sure that it meets the standards and processes against the appraisal document we have and address any issues at that point.

Personally I will be handling a number of other activities. For example, I'll be working with our partner and client services department to continue to select and train additional lead appraisers as we grow and scale this program.

I'll be working on the engagement between participating organizations and our lead appraisers form that initial introductory call to scoping the appraisal with the executive sponsor to determining schedule and costs.

Additionally, I'll be working with the incoming appraisal data making sure it's collected in a protected way, distributing it to the appropriate parties at the limited -- different limited views, anonymizing it and working with the trends.

One of the things we're looking to do as we continue to grow and interrate this program is through the MDIC we're looking to sort of shift from the four maturity model working groups that we currently have into a single focused core group that involves all members of those original groups.

This core working group would be able to

then look at the metrics associated with program adoption, program effectiveness, and the feedback that we receive from surveys after the appraisal.

They can then use this data to look at areas of concern or need and focus, tackle them based on highest priority. That way we can continue to iterate the program so that it is the best that it can be.

Of course, as a pilot there will be a lot of learning, there will be a lot of growing, and that's what makes this so exciting. So, of course, as the core group makes its iterations, brings it up to the steering committee the CMMI Institute PMO will adopt accordingly and modify our documents on the right here from our operations playbook to our appraisal playbook to all of the training to the FAQs to onboarding material, all of that good stuff.

All right. So I know George kind of went into this a little bit, but let's talk about what an appraisal actually looks like at a high level. So the first phase is planning. As you saw in the previous slide, our goal for this was 30 days. But depending on the availability of the executive sponsor and our

lead appraisals -- appraisers this is looking actually more like 30 to 60 days.

So during this time we'll be scheduling meetings to discuss what do your different products look like, what do your different product lines look like, what do your operations look like and this helps us to determine the scope of the appraisal and specifically how we'll sample all the different areas of your facility.

That determination will then help us figure out how much time we'll need to spend on site with your organization. Specifically what the appraisal plan will look like, which departments we'll need to set up interviews with, what days we'll set up those interviews and collecting your quality metrics form.

All right. The next step on site. What we've seen so far is that this is looking like it'll be about five to seven days on site. And in order to be respectful of everyone's time we are trying to keep it that way.

On site will have two appraisal team members at least conducting those interviews with the

different departments. And after they are done with the interviews they will collect all of that information into their findings.

Once they have their entire findings they will then go back to the interviewees and validate their findings, make sure that they're on the same page with everyone who's working in your facility so that everyone understands correctly what is happening.

They may also collect documents as needed to verify what it is that the interviewees have told them. This might be standard operating procedures, it might be graphs, whatever kind of evidence might be needed.

Once they have validated their findings they will then present these final findings to the entire organization. This will include areas of strength, areas of weakness, suggestions for improvement, maybe even a plan for continuous improvement sort of based around these checkpoint which I'll talk about in a minute.

After they have finished presenting all of this they will then go back to their findings and

remove attributions. By attributions I mean the names of the specific people they interviewed, the names of the specific projects that they looked at, any kind of identifying material. So they'll remove all of this and then send that to the CMMI Institute PMO either in encrypted or password protected format.

All right. So let's talk about the checkpoints. This, in my opinion, is one of the key pieces of this pilot. It's at this point that the lead appraiser will regularly reach out to the organization to see what's changed since the last time they've spoken.

This gives organizations a chance to discuss their activities, ask questions, raise concerns, validate what it is that they're doing, and potentially update their heat map to see how they've improved or where they are falling behind.

Okay. So how are we going to assure that appraisal to appraisal they're performed consistently? This is a question we've seen a few times and I'm sure some of you may have had your drastically different experiences with auditors from auditor to auditor.

So before I get into how specifically these program appraisals will be done in a consistent, objective way let me first talk about how the CMMI Institute assures this across all its appraisals generally speaking.

So first we only have about 380 lead appraisers in the world. It's a very select group of people and requires a multi-year investment to obtain that certification.

To become a lead appraiser an individual must complete our intro to CMMI course, our advanced applying CMMI course, be on two to three appraisals, and then submit an application.

In that application they must prove that they've had at least ten years of managerial experience specifically related to the creation of a tangible product.

They must also have at least two years of experience managing technical personnel ranging from training to facilitating discussions to doing presentations.

Now if they pass the application then they

must be observed on an appraisal. This means that they will be leading an appraisal while one of our experienced subject matter experts who is also a lead appraiser watches them take notes -- takes notes, observes, and then makes a determination as to the quality of their work.

Once they pass that observation then they will receive their certification. Even then, however, every appraisal that they conduct they must submit the results to the CMMI Institute for a quality review check.

At this point our quality analysts look at the results, look at the way they found those results, and make sure that everything was done according to the method definition document that outlines the expectations, the procedures, the requirements for each appraisal. If issues arise, we address them immediately and, again, deal with any conflict resolution at that time.

Now for our specific group of lead appraisers we have chosen from people who have had at least -- who have been on at least 30 appraisals with

a record of exemplary performance in their appraisal review history. So all these people we've monitored their results and we know that they are some of the best.

They come from credible backgrounds like Lockheed Martin, McKesson, the U.S. Air Force. And additionally we're also going to make sure we equip them with very specific guidance. We will provide them with their own version of the method definition document, an appraisal playbook, a template for how they will make the appraisal plan, a standardized appraisal data collection tool and heat map, and very standardized training so that they each understand this program, what the goal of this program is, what the expectations are, and how these appraisals are specifically intended to be performed.

To further ensure quality we will make sure that there are at least two appraisal team members on every appraisal to reduce the subjectivity that can come from a single person. They'll each be there to sort of check on each other and keep each other accountable.

The other advantage of having at least two members is that we can make sure that the team has a combined knowledge of significant medical device experience.

And, of course, after each of these medical device appraisals are completed they will go back to the CMMI Institute for a quality review check against the specific method definition document for this program. And, again, if there are any issues or any conflicts we will resolve them then.

MR. ZACK: Thanks, Kim. So one of the -- first of all, I notice some people holding up the iPads and taking pictures. All these slides will be available to you afterwards. So you certainly can take pictures, but the slides will be made available.

One of the tools that we will be using in these appraisals is what we've called the heat map. I've heard some people call it the Rubix Cube, the Chicklet chart, whatever you'd like to call it.

Essentially what you see here is the practice areas or the process areas that have been determined by the working groups to be in scope for

these particular appraisals. So you can see there's 11 of those on the left. And then this is just a sample of what a heat map could look like at a baseline.

So those numbers on the top represent specific practices for each of those particular process areas and then, as you may gather, it's a red, yellow, green chart indicating where for those particular specific practices within those process areas whether that has been satisfied, is partially met, or if it's deficient.

And for each of those -- so, as you may guess, for estimating there's a practice 11 in this particular example. How that's been described that organization for that particular practice -- I'm sorry, for that particular product that they were looking at they would -- they've determined that's satisfied.

If -- as another example, if we were looking at planning specific practice 21 you see there's a partial there. That indicates -- and this is all defined in the method definition document that Kim was

referring to that indicates there's some elements of the practice there, but there are some deficiencies that need to be noted to meet the intent of that particular practice.

And so for the organization that's getting this partial in this particular specific practice for that process area on a product line there would be a corresponding statement, a finding that would indicate this is what is -- this is what's of concern against that particular practice area.

And then finally the D, the deficient that would indicate there's no evidence or it's not being implemented correctly for that particular piece.

Now what you see on the right to the far right is then a manifestation of that into a set of scores or averages that then actually roll up on the top to an overall average.

So this is what the organization gets at their -- one of the things that the organization gets at their appraisal at the conclusion of that initial appraisal, that benchmark. It gives you an indication as to how you're performing against these particular

processes, these capabilities within the CMMI framework. Every organization would get these for these 11.

Right. So Kim's noting to me that, you know, in addition there's a couple ways that we determine from an appraisal perspective how something is satisfied, partially satisfied, or is deficient. It's a combination of interviewing the people that are actually performing the work to assess their understanding of that particular practice and it's also review of the documentation that is supportive of that. So it's a fairly holistic view.

Now this is, again, this is what the organization gets. The next slide you see this big, black square. This is what's essentially redacted. After it gets passed to the CMMI PMO this is what gets passed over to the FDA.

So the FDA has indicated they are not at this time interested in all your specific results and all your individual concerns and where you're partial or deficient. They're interested in the overall scores to get visibility into how the organization is

performing at a more holistic level. But they expect the organization to be tracking those findings and taking care of those particular findings. So essentially not interested in all the laundry underneath, but essen- -- what's going on at a system level against these 11 practice areas.

Yeah. And another thing Kim has reminded me of is a common question here is people -- and this is very common in organizations in the device world y'all want to know what score you need to get.

The reality of it is at this point is the FDA said we are not interested in a specific score. You do not need to achieve a specific score to receive the regulatory modifications at this time. They're interested in your involvement, they're interested in you assess -- going through this assessment by which then you have a foundation by which you can improve.

So even if in this case where we see for requirements development there's a 36 percent score, that does not necessarily drive your involvement or the modifications that you receive in this particular program.

Okay. That is in my experience in speaking with various device manufacturers it's very hard for the compliance focused mind to get their head around that. People want to know what -- how do I get my B-plus so that I can get the particular results. It's not driven that way with this particular program. Again, it is baseline where you're at and then improve from that.

Separately we're also -- in this program each organization will be providing a metrics collection form. This is something that our measurement working group defined with industry, with the agency to collect the measures for your organization, for you facility, for your particular quality system.

So this is going to be individual to your organization, to that facility. It's going to be dependent upon what functions you have at that facility. So obviously if you're -- if that facility is R and D only, that's going to be different than an organization that's doing manufacturing only at that particular facility.

So these scorecards will not necessarily be able to be trended in the same way as the prior ones from across all organizations, but will be specific to that organization. And what it'll allow us to do is see how that organization is progressing on data such as complaints, CAPAs, scars, your traditional compliance metrics that you might be using in your quality system to meet your particular objectives.

It's an aggregate of all the products at that particular facility. It's not for the individual products. Again, it's specific to that organization. It's going to be very much dependent upon how you collect that data, your tools, the function of that particular organization. And, again, we're looking for that to be driven -- we're driving that to measure the specific progress of that organization over time.

This is something that the organization will self-report back to the PMO on a quarterly basis and is shared back with the -- back with the agency.

There are -- so obviously this is -- there's tools and templates and instructions that have been put together and examples of how to collect these

data. Most of you may have very good insight as to how you would like to already fill out this card for that particular organization. Others if you're not certain or if you're struggling there's plenty of examples. And this is a part of the -- the planning and the appraisal process to collect these particular sets of data.

There's a good point here that it's appropriate for an organization to demonstrate -- we'd love to say by way of involvement with the maturity model you're going to see these data trend in a positive direction. But there's a story that's going to go with that, right.

If you're changing your tools, if in regards to particular findings you've decided to change processes you may see data stagnant or even go in a negative direction. But there's -- it's is a metrics collection form to facilitate that conversation between the organization and the FDA in regards to your continuous improvement journey.

But over a long period of time obviously or a longer period of time we would like to see progress

on these data to demonstrate an improvement in quality.

So we talked a little bit about this in the prior slides, the checkpoint process. And, again, this is the check in with the appraiser and the organization to encourage their continuous improvement and encourage engagement in the program.

It would be very easy to do a baseline appraisal and then not come back for a couple years and see how the organization is performing against their -- against the CMMI framework again, but that would not be necessarily effective or really driving the goals of this program which is to stay engaged and to drive the continuous improvement that we're looking for for the organizations participating.

This allows the organization to check in with the appraiser to say, hey, we think we'd like to drive the improvement in this particular direction. Does that seem to make sense against the framework? Is that really aligned with the business value add that you're looking for?

These would be occurring every six months,

but we think that they could -- depending upon the organization they could occur more frequently. They could occur quarterly. And then that heat map Chicklet chart that we showed you previously that is also as appropriate updated as the organization demonstrates progress. And that, of course, is shared back with the CMMI PMO for that trending and that data collection as well as -- as well as the FDA in that -- the identified fashion.

The checkpoints occur remotely over the phone, digitally. This is not yet another onsite affair. And we're expecting each of those engagements to be somewhere over the course of an hour or two hours depending upon the nature of the discussion.

I have -- I've had the opportunity to work in medical device organizations where I've been on audits and inspections and I understand the nature of that particular activity. I've been in the front room and I've been grinding the bone in the back room, as well.

And I have also been on hundreds of CMMI appraisals in the device space as well as in other

industries and these are significantly different activities. A common question we get is how is this different than just some other FDA inspection?

The primary difference that I could describe to you -- and there are -- there are members here or participants here that have been involved in these appraisals that you can also hear this from later on today is that it's really a focus on the organizations capabilities. It's a focus on how the organization can improve those capabilities to increase the value add to the organization in those core metrics of quality, customer satisfaction, reduction of rework.

This is obviously something much greater than compliance. Obviously, as Dr. Shuren said earlier, compliance is important. It's necessary. It's just it's the baseline expectation just to be on the field of play of being a medical device manufacturer. You have to be compliant, but this is something greater than that.

I'd like to tell the story that the difference between compliance and quality is I have a -- I have the old person experience of having a 16-

year-old son. He demonstrated compliance the day he got his driver's license. That does not make him a quality driver. He thinks he is, but there's a difference obviously.

Additionally with these -- these device appraisals these are interviews with the people that performed the work. This is not necessarily that front room experience where you're just putting your quality director in the front room or your legal representation just to answer the questions as to how SOP 1234 is in compliance.

This is executing those appraisals to understand how the work is performed by the people that do it to see if there's opportunity for improvement to drive greater levels of quality in your organization.

So all these things drive a conversation of how to improve the organization in way that makes sense for that particular business. It's not just a corrective action list. There's outputs that might look like that, but it's not just a corrective action list of punch these things to get this particular

score. It's, again, a driver to improve the quality of the products and the outcomes of the organization. It's something beyond compliance.

MS. KAPLAN: All right. I'm sure this is one of the big questions on everyone's mind. How much does this program cost?

Well, before I get into that I just want to quickly touch again on what this program covers and encompasses. First and foremost, the appraisal. As we've discussed, this has a lot of different moving pieces in it that can take place over the course of several months.

We also are covering the multiple checkpoints meant to drive continuous improvement. Because these checkpoints may be where most of those conversations on how to continue to improve occur we wanted to make sure that they could happen with the -- without the organization incurring any additional costs.

And, of course, program management you've already seen there are a lot of different touch points from enrollment to training to looking at the

appraisal data to trending.

So what are the two factors that will influence the cost? The first one is the number of different product lines or different processes that you have in your organization.

The way the model works is that we want to look at each of the different things you do and appraise that against the 11 practice areas you saw earlier. So depending on how many different areas there are that we'll need to look at that informs how long all the interviews will take, how many interviews we need to have, how long we'll need to spend on site and that's where the bulk of the cost comes.

Another variable is the number of appraisal team members we might have on the appraisal. For example, it might make more sense to have an appraisal occur in one week with four appraisal team members rather than over the course of two weeks with two people. It would be the same cost, but it saves everyone a week.

So what we've seen so far with the six sites that we have enrolled currently it's looking like a

range of a total cost of about 25 to $35,000. Now this is a pilot. The costs are a learning experience and they will probably change, but the important thing is that we're willing to adapt so that we can remove any kind of cost barriers that we see for small organizations.

For example, one of the things we're currently looking at is a tiered structure that follows a similar model either to MDIC or FDA so that way the cost for your organization is appropriate.

MR. ZACK: So I would offset any cost conversation with I think some of you have heard the studies that were presented previously. Boston Scientific in regards to some of the manufacturing modifications that they were discussing they discussed a save -- a cost savings of about three quarters of a million dol- -- three quarter of a million dollars.

We also did a survey as to what would you save if you were not undergoing an FDA inspection and there was a lot of variability in that survey. Organizations put that cost savings anywhere from $10,000 to half a million dollars.

I don't know how you capture the stress maybe associated with an FDA inspection, but it's -- I think it's a significant part of the cost, as well.

Okay. So our current timeline. So what we've been working on this summer and through quarter three here is the -- completing the definition of this -- the operations of this particular program.

Again, there is already an appraisal method. There's been thousands of appraisals executed, but we're dealing here with an engagement between industry and a regulatory body in a pretty unique way. And we wanted to make sure that that -- the handoffs there between all the parties were well defined so that was the primary focus of our working groups over the summer.

Of course we had the FR announcement by the FDA in July and that has driven the enrollment of, as Kim said, six facilities. And were -- we've been having those initial scoping and scheduling conversations to see if we can land on appraisals here in the last quarter of the year with those particular early adopters.

So our goal for the remainder of the year and into 2018 is to execute those early adopter appraisals, to take on any others that we can potentially get into from a schedule perspective.

And we have said over -- you've heard it from Dr. Shuren, you heard it from Cisco, and you've heard it here in this presentation is to execute, inspect, and adapt and make this a more effective and efficient program and refine it.

There is a link there to the CMMI Institute which will bring you to the enrollment form as well as FAQs that you may have.

This timer is wonderful, but also insidious. We have it seems like plenty of time for questions so, yeah. It was at like six minutes at one point. Now it's back to 20 so thank you for that, Jennifer.

But we'll entertain any questions that -- we have some time here for questions right now, any questions that anybody has.

MALE SPEAKER: Hi. Given the scope and depth of information that you provided it seems like there'd be a lot of value in having an operating

manual for participants that captures the kind of information that you've provided today in your slides and in your comments.

Does that manual exist? If not, will you prepare one and will that manual be available publicly so that potential participants have a chance to look at it?

MR. ZACK: So at this point there are -- there's an operations playbook and there's an appraisal playbook that have been in work by the working groups. The closest thing that we have to a manual for the public, the participants is really the FAQ as well as the description of the -- of the CMMI model.

It's certainly something that we could -- the FAQ is something that is always getting changed. Frequently asked questions seem to extend to each person's individual questions and so that is something that is -- that's being extended upon.

Kim?

MS. KAPLAN: Yeah. I also want to comment on that. So we are working on something. It is in

the works. We are planning on having a pre-enrollment informational brochure as well as a welcoming/onboarding packet for organizations that are approved into the program.

MALE SPEAKER: So just a quick follow up. You mentioned a playbook and a manual that have been prepared. Are those publicly available for prospective participants?

MR. ZACK: The -- the -- so they are -- at this point the short answer is no. The appraisal playbook is -- is a very dense document. The method definition document is in excess of 300 pages and the descriptions on that are details that are really specific to the -- to the appraiser community.

The operations playbook for the Institute speaks to, hey, when Kim gets the enrollment form these are the things that she needs to check off. Those are really internal documents to ensure the consistency of the program.

But to your point and your question public facing documentation is being further created.

MS. GEORGE: So I'm Elizabeth George with

Phillips. And, first off, thank you. This has been very informative and I think it is a very valuable program.

The question I have, though, is is that as a manufacturer we have a mandatory that we have to MDSAP with IMDRF. And those of us that have radiation-emitting devices also have to do the RAD health inspection.

So we're already mandatory on those and now here's another inspection again that we have to pay for potentially if we decide to join it. So what are the thoughts either from the FDA or from you guys of trying to integrate more of those activities together?

MR. ZACK: So this one -- this is not an inspection. I see you getting up. This is not an inspection. And, two, this is -- as you noted, this certainly is not mandatory.

Cisco?

MR. VINCENTY: Yeah. So that's a great point and it's something that we are cognizant of. We've got a lot of activities going on right now. A lot of different variance, a lot of different options.

One of the things that we will be actually making public with this is a better description of what all those options are, what the benefits are, what they entail. But that really comes and boils back down to a business decision, right? Which is the right avenue for you?

The idea here as this evolves there's opportunities for these things to start to align, but we are learning through this process. MDSAPs already operationalized, the RAD Health Program just serves its distinct need.

As we keep moving forward we'll find the ways and opportunities to start bringing these things more into alignment and bringing them together. But I understand that pain point. We've heard that one. We want to make sure that, you know, we're cognizant of it. We're going to try to make this something that is at least flexible enough in the beginning and we'll try to go on from there.

Just another quick highlight to Steve's question about the playbook. This is also something we discussed internally to try to figure out if we

were going to make this public and when it's ready. But we are adapting it a lot as we keep learning through the early enrollment.

So, you know, one of the discussion points that we had was really trying to avoid a manufacturer going in and trying to basically set themselves up instead of just letting themselves be found and find out where they are in benchmark, right, because then you drive different behaviors.

So the practices you could probably get detailed information on and that could be made available, but I think the playbook and all that stuff until we've got that more settled out throughout the course of the pilot that's probably going to stay.

MALE SPEAKER: So and the other thing that I wanted to add was just to consider that there are different incentives to participate in each of these different programs. So currently the MDSAP program relieves you -- or replaces a routine surveillance inspection.

This program, as we'll discuss over the course of the day, provides different regulatory

relief or relieves you from different burdens that FDA places on industry. And I think through those regulatory incentives and really more importantly through the presentations on how industry perceives return on investment in participating in a program like this is really where we think you'll see the value in participating.

MR. SNELL: Good morning, I'm Todd Snell from NxStage Medical. You know, I really commend you all for the CMMI model. It's really interesting coming from industries other than medical device earlier in my career these were concepts and things that were being pushed quite a bit in aerospace and automotive.

The question I have is a number of organizations have followed the Malcolm Baldrige approach or the EFQM model in Europe. That seems to be a lot like CMMI from a model perspective.

Have you compared or do you understand maybe possibly the high level of differences of those models versus a CMMI?

MR. ZACK: Frankly, the short answer is we

-- I've not a recent comparison of those. I know that those have been referenced here in the past. I think one of the biggest issues that we've heard about it and one of the ways that we've tried to adopt -- adapt this particular program is with -- as you're aware with CMMI there's an approach that you can take to attain a specific maturity level, a specific rating.

We are very much trying to take this with a different view of the model using a continuous approach as opposed to a staged or a maturity model approach so it's not just achieved some particular outcome and then you're done.

I think that's the primary difference that we've heard, but we can certainly do -- I'd be open to hearing and discussing with any of you any concerns that you have about that particular program or lessons learned from it.

MR. SNELL: Yeah. The major concern in Baldrige is the business results.

MR. ZACK: Uh-huh.

MR. SNELL: And so as companies go through good times and bad times Malcolm Baldrige can be

actually at times kind of daunting if you have a bad year or a product doesn't launch the way you expected or get received by the market.

And so companies that have gone through Malcolm Baldrige if they're in a downturn or a down time it's very hard to stay at that level because of the business results that are part of that model.

Does CMMI touch business results or is it more practices?

MR. ZACK: The practices that we have in scope at this point do not specifically tie to the business results. And, frankly, I think in dealing with organizations that are small versus large it would probably be a little challenge to normalize that. So it's separate from the -- the areas that we have in scope for this pilot program.

MR. SNELL: Thank you.

MS. KAPLAN: Just in addition, the CMMI model tries to take a look at what it is you're already doing and how that fares against the best practices in that industry. So we're not necessarily trying to ask you to do all these other things to meet

a certain expectation.

MS. STENSTROM: So Dawn Stenstrom with Boston Scientific. Thank you for your presentation this morning. I thought it was very helpful and informative.

Since one of the foundational elements of this program is really to be able to communicate quality of products to patients and caregivers and medical providers I'm curious if the pilot program is also going to be including some sort of feedback for information sharing to that -- that consumer base. And, if not, why not?

And could you say a little bit more about what information is shared to other industry programs using CMMI?

MR. ZACK: So, yep. So our experience has been is that different stakeholders those being appraised have different expectations as to what they want to share with their -- with their consumers.

And there's -- we are not assuming anything for the -- for the industry. So if you as Boston Scientific want to advertise your involvement in that

program, absolutely, go for it.

If instead you don't -- in fact, in creating these slides we actually had who had enrolled first and we said, you know, maybe they don't necessarily want that to be broadcast at this point.

So the CMMI Institute and the PMO are not necessarily going to at this point broadcast that information without permission from -- from the device manufacturer.

Does that -- does that address what you're looking for?

MS. STENSTROM: Yeah. I'm curious, you know, you shared how the results will be shared, you know, to the manufacturers and also to FDA. But as we look more broadly it might be worth considering how manufacturers might share this information with patients and caregivers.

MR. ZACK: Absolutely. And so that's I think some of the trending that we were talking about which is after we get a certain number, a certain body of appraisals underneath us and we can start to look at the data to say, hey, we're seeing that these

particular practice areas this is where medical device organizations perform well, these are how it's tied to each organizations improvement and quality, these are areas in which they did not necessarily show strength but the participants collected together solved that particular problem, put these particular steps in place.

I think that absolutely represents an opportunity for those participants to advertise that back to their consumers to say this is one of the ways that we are addressing quality to make it better outcomes for our patients.

MS. STENSTROM: Yeah. I think that's helpful. I think there might also be opportunity to maybe do focus groups because communicating to that audience is a little bit different than other audiences as you noted earlier.

MR. ZACK: Agreed.

MS. KAPLAN: I don't know if this is also helpful, but you asked how we communicate sort of the results to other industries. We have a maturity profile that goes out biannually and that kind of

gives an overview of like statistics on how are the different sizes of organizations that are involved, what -- what kind of improvements did they see.

And we also have on our website a list of case studies so organizations that have chosen to utilize our standardized capability awareness program packet and it lets them track down sort of their metrics.

And like, for example, an organization might see a 60 percent reduction in defects and that's something that gets published and that -- an organization could potentially share with their patients, for example.

MS. STENSTROM: Thank you.

MR. ZACK: Thanks.

MR. VINCENTY: So just to add onto that we do have plans as this starts to evolve and there's actually also ongoing work through the outcome analytics team that is really putting together what we've determined and we've engaged with which is some of the value added proposition to patients.

And that's coming up in the more 2018/2019

time frame. What we did have and it's a great point and question and I'd be interested similar to George in engaging with the manufacturers because it was a point brought up last time by one of the patient advocacy groups, right.

There is this trust element and there's a potential maybe within this to help move that needle. Figuring out what that is and what really is of value because they really don't care a lot about some of the behind the scenes things, but there are some key elements that we can probably make available.

But understanding what those are, as you mentioned, is probably going to take a little bit more time and we could probably evolve down that path.

MR. KEHRER: Hi. I'm Aaron with In2being. Thank you again for the presentation. This has actually been really informative and helpful.

About 90 percent of the companies we work with are new to the medical device space. And so there -- and predominantly in kind of the premarket position. Looking forward into the future, you know, after the pilot program, you know, goes through are

there going to be resources available to help educate these people new to the space that are developing new products so that they can be in a good position for when they want to do a CMMI appraisal?

MR. VINCENTY: So the -- sorry. We're trying to tackle in between both sides, but that is also one of the main goals. The beauty of the model we've got 11 practice areas we focused on.

As you start expanding some of those areas probably hit more valuable to the small innovator space. They've got a different need so we've got to figure out exactly what that piece is.

And we've started that engagement really -- really learned how we can adapt to provide that portion and that education element to them and then see how we can kind of incorporate that down the road. But, again, we're looking next stages.

MR. KEHRER: Okay. Yeah. That was kind of my big question is sort of what's the future look like for these folks.

MALE SPEAKER: Hello. Yenfak (phonetic), Nessun Aeronautics. We do accommodation products.

And my question really relates to this program. Does that involve also other centers of FDA or is it solely CMMI PRO (sic) and CDRH?

MR. VINCENTY: So right now for the pilot stages it's really just a CDRH activity. We've got interest from companies who do play in the accommodation product space.

If they've got the device elements that are covered strictly under CDRH purview we can cover that probably under that piece, but we can't really cover what's going on with the drug space. We're still learning on our end before we start talking about expanding to other centers and their approaches.

MALE SPEAKER: So did I hear you say that the pilot does not include other FDA centers, but --

MR. VINCENTY: Correct.

MALE SPEAKER: -- you expect to give a recommendation for any --

MR. VINCENTY: As we learn and we evolve, yeah, we'll keep -- we are actually -- they're engaged with us and we've been talking back and forth and kind of learning from each other's experiences so.

You know, as we move forward they'll be kind of watching and we'll see where it goes from there.

FEMALE SPEAKER: So I just wanted clarification for you. I'm a large company, Imagine, and I've got many, many sites. Can I decide it's just going to be this site or this group of products that participates in the pilot?

MR. ZACK: Yes. Yes. So it -- it is -- we're -- we're looking at it by a facility because the modifications that are being provided by the FDA are associated with a facility.

If you were to say I just want you to look at this product within a particular facility, I think we'd have to have a conversation with Cisco and his team to determine is that an appropriate sample from that facility for you still to get the particular benefits that are associated with it.

So we're typically looking -- within the large organizations we're looking at a particular facility so that the benefit -- the appraisal can occur there or sampling from that and the benefit can be provided to that particular organization.

MR. VINCENTY: I think we're running short on time. Got one more question you ready for?

MALE SPEAKER: Sure. So you didn't go into the details of the capability maturity model itself, but just going on some things I remember from being involved with it years ago related strictly to software development a big aspect of the maturity model is repeatability.

MR. ZACK: Uh-huh.

MALE SPEAKER: And how will that play in? I know you said that, you know, getting a certain score is not really the goal of this. But, you know, there's going to be a significant focus on that whether you want there to be or not.

So companies who by their nature are more immature even, you know, new companies, startup companies are going to by definition not score as well on certain parts of the model. How will that play into your ability to attract those companies to participate?

Is there a way to kind of pair up the maturity of the organization with the score they get

on the model, itself?

MR. ZACK: So I think that there's a couple -- there's a couple questions that you have within there. So certainly we are assessing -- as a part of any particular process we're assessing an organization's ability to have that process be managed, defined, repeatable. That certainly is -- there's an aspect of it.

There certainly is an aspect of this by which we're indicating whether any particular practice is satisfied, partial, deficient and it's defining a particular score.

We recognize that some organizations, particularly low capability organizations, are usually a bit more tied to the score than high capability organizations. That's been my experience. They're more interested in the improvement.

Part of the reason for the checkpoint process is to not necessarily take your eye off the ball of that particular score because that might be very hard to do, but instead to work with that organization, to engage that organization, and drive

that organization in a way to improve in a way that makes sense and not necessarily just drive it to the score.

I have definitely seen organizations that when you do the appraisal they're just exclusively focused on the score and they want to get that to that particular 100 percent. And they often define themselves around an axle that does -- that's not necessarily aligned with the business value.

I think this ties back to our appraiser selection that you heard Kim describe which is making sure that we pull in appraisers that recognize the system of the model, the framework, and continuous improvement so that it's not just about getting an 80 percent or a 90 percent.

It's -- frankly, this conversation is one of the toughest things that I see in this entire conversation. People in the compliance mindset just give me the checkbox of things that I need to do versus the actual improvement mindset.

And so it's going to take that interaction with those organizations, the appraisers, faith from

the agency, and that sort of transparency to help drive that culture of improvement.

I know that's not necessarily like the put the pin on it button answer that you might be looking for, but I think that's the culture that we're trying to drive towards.

MALE SPEAKER: Okay. And then just one quick follow-up question. You mentioned the appraisal selection process, appraiser selection process. How is -- assuming this program catches on and, you know, it's voluntary but if there's some real benefits and I think I'm kind of waiting to hear what those are maybe later in the agenda.

But if it catches on how is CMMI going to keep from becoming a bottleneck?

MS. KAPLAN: Sure. So right now we're working on, again, standardizing rigorous training. And as we continue to scale and grow in this program we have certain I guess thresholds at which we will change our structure a little bit and open it up for other people to apply to be an MDAP lead appraiser rather than us choosing them selectively.

And, of course, that application process will, again, have to meet our high expectations of an exemplary record of quality reviews.

MR. ZACK: So I thank you all for your time. I know there's probably many other questions. We'll -- there's a panel later on that we'll also be sitting on. We'll be here over lunch. Be happy to entertain any of your questions.

The only closing thought that I have is it is not a violent process as was referred to by the head of CDRH earlier so thank you very much.

MR. VINCENTY: So thank you. You know, George and Kim will be available all day so if you've got any follow-up questions or anything else to bring up or want to bring up the questions later in the afternoon session, we can tackle and address them from there.

So I'd like to introduce next Robin Newman. She's the director for our Office of Compliance. She's got, you know, a varied background industry experience so she brings a lot of her perspective in here.

She can actually go over and kind of run through what we're looking at from an FDA interaction standpoint over the framework for this pilot.

MS. NEWMAN: So good morning, everyone. Again, I'm Robin Newman. I'm the director for CDRH Office of Compliance. And just for a very short time here I'm going to give you a real basic overview of the framework for the pilot.

So, first off, I want you to understand a little bit about kind of where this comes from. When we look at this as an agency -- and, you know, you heard Jeff talk about the fact that we understood that there were companies in compliance but they still weren't necessarily meeting their quality thresholds.

At the end of the day when you think about the focus of this agency, when you think about the CDRH strategic initiatives and the focus on the patient which is just -- which is key to everything we do that means that that standard is not acceptable.

So being compliant is just a ticket to ride. Being good at what you do, being -- making a good product that really makes a difference in patient

outcomes that's really where we're trying to go with this particular program.

So what we're trying to do is create a really collaborate learning environment where not only industry and MDIC and, of course, the CMMI assessors are talking, but we're also listening to patient groups. We're also trying to hear and see what's happening in the provider environment to try to create the best and most robust program possible to move us behind the compliance situation.

In fact, the goal would be if this is good, and we believe it will be, and this program achieves what we believe it can achieve, compliance will come naturally because you will be doing the things it takes in order to create a high-quality program. And that's what are regulations are designed to achieve. So that's what we're looking at.

So what we're going to talk about today is we're going to talk about governance on the pilot briefly, I'm going to tell you a little bit more about why we chose maturity, a little bit about the pilot goals, and then how do we achieve this learning

mindset and what's the agency, industry, MDIC and all of our colleagues trying to achieve here.

One of the things I think it's important to understand is that this is a pilot which means that we don't know everything yet. So I know everybody's eager for information and they want the answers, but that's the whole point of doing a pilot is that it's okay to go into this not having a lot of the answers.

And you're going to hear from Cisco and Sean a little bit later about how we're going to enable it. Cisco will talk to you a little bit about what those incentives are we think as an agency that we can bring to you to participate in the pilot.

But what this really requires is open communication, open collaboration so that we make sure that we're sharing information. We need to be as collective and as engaged as possible on all -- on all fronts.

And I want to assure you that CDRH is committed to doing that. It's committed to that open and candid dialogue with you. One of the things you heard George and Kim talking about is that this is not

an audit.

It is not an audit. This is an assessment of your company's capability to be a learning, growing, quality-minded organization. And by -- that's why the score, the initial score is not terribly important. What's important is what you do with that information. What's important is how you as a company can engage with the CMMI assessors in order to get into that qual- -- that continuous quality improvement loop.

One of the most important things that we require is that if you want to be a member of the program you have to have had a successful audit -- and by successful I mean NAI or VAI -- in the last four years. This tells us that you're basically a compliant organization.

So that's the entry level, basic compliance. And what can you do beyond that? That's what we're trying to achieve with this particular pilot.

So, again, we're not going to have all the answers and that's okay. We're going to learn as we go. And the -- and I think that what we want to do in

order to make this happen is keep and create and environment that's very transparent. And honestly the phrase we use internally is I want to create a safe space.

I know we're kind of scary people at the Food and Drug Administration, but we don't mean to be. And I will tell you just so you understand my background I'm actually a nurse practitioner. And I spent over 20 years in industry before I came to the agency almost two years ago. So I know where you sit. I understand what your concerns are.

I've been a healthcare provider, I've been a research coordinator, I've been a research monitor, I've been a head of quality and regulatory, head of clinical affairs, I've done a lot of these different roles, worked in R and D. And so I understand the challenges that the agen- -- that you as a company have to deal with and I know how it feels when the FDA comes into do an audit.

I, too, have been in the front room, in the back room, in the side room, you know, and been through that a lot. I know how intimidating it can be

when you find out that the Phil Panacos (phonetic) is going to be your auditor for the day. So he's one of our national experts, by the way. So I understand this.

And what we want to do and what we're trying to achieve for you on this end is to create the most transparent, collaborative relationship that we can. And I -- those of you that have heard me talk before I've said this before.

So if you think about the spectrum of relationships that you can have with -- between people, between companies, et cetera, you can have like mortal enemies on one end and you can have best friends on the other end.

Well, the truth is we don't want to be in either one of those spaces because as a regulatory body that's not good for us and as a company that's not good for you. What we're looking for is that middle space that we call trusted colleague, trusted colleague.

So what this is really all about when you think about Case for Quality is about enhancing

trustworthiness. If you're a highly trustworthy, high integrity company you're going to be very answerable not only to any federal regulator that comes along, but to your customers, to your patients, to the providers that use your products. This trustworthiness is really the key that we're looking for.

When you think about the world of healthcare how many of thought 15 years ago that you would be able to go on Health Grades and see -- and look at actually a rating of your hospital or your care provider?

But you can today. And that's where I think when somebody mentioned earlier where might this go I think that's where we could go with this at some point. There could literally be a process where as a manufacturer you have a rating, if you will, that says I am a trustworthy, high quality, high integrity organization and you can count on my products. So that's kind of where we're hoping to go.

Communicate, sharing, and then ultimately let's drive improvement, not just compliance.

Because, again, compliance is just the ticket to ride. I want to be a good company. I want you to make good products. I want us to not worry about you as an agency.

If you really do this well and we do this well together, the agency does not have to spend resources monitoring and auditing your particular organization. We can figure out some way to create a sort of scorecard that comes in or an annual check in with us or a biannual check in with us of some kind so that we know you've still got it.

And that doesn't mean you'll never have problems because you will. Every company does. Every now and then there's something that goes wrong in manufacturing. But it means that you have the capability to address that in a proactive and very efficient manner.

So we're not expecting perfection. We just want to see process to- -- and progress toward improvement. Continuous quality improvement. I heard that a lot, said that a lot in my days as the VPQ a Siemens and I'm absolutely still committed to that

today. Progress toward improvement.

So the way this works is the pilot will have a governance committee. All projects need a governance committee to make sure they stay on track. And you can see this is the Food and Drug Administration, the MDIC Case for Quality steering committee, the CMMI Institute, and then the -- that will work together the pilot program.

Recognize that the steering committee from MDIC is made up of people who come from the various stakeholder groups. So these are working together to create the pilot governance.

So the leadership of the governance will be primarily this. And we will evaluate or I -- this particular governance body will evaluate the progress of the pilot.

One of the questions that comes up is what happens is someone needs to off rim? You're in the pilot, somethings going on, some major event occurs and you need to off ramp. This particular steering committee will work with companies in order to make sure that that can happen effectively and efficiently

so that's going to be one of the things we want to look at.

Now Sean is going to really cover the rules of engagement when he gets up to talk in a few minutes. And Cisco's, again, going to walk you through the incentives that we're looking at doing.

But the most important thing, again, responsiveness, early communication, and a key safety focus, risk focus around what we're doing here. We're not watering down anything.

You know, one of the questions that sometimes comes to me is, gosh, if you're not focused on compliance so much aren't you just like watering down the whole process?

Oh, contraire. What we're trying to really do is move that needle further upstream so that the quality capabilities of the organization is so high that I don't have to worry about compliance because you will have the necessary maturity and ability to get into compliance if there's some sort of a problem in your system. So that's what we're trying to do.

And the pilot will help I hope teach us

where it is that we need to focus and the things we need to do. One thing you may have understood from the conversation you just heard from Kim and George is that this scope for the first point is just on the -- on sort of a narrow strip of some of the things that CMMI could assess for your organization.

Over time it could be that this is a much broader assessment that you engage in. And what the feedback I've gotten anecdotally from companies that do this is that they learned so much about their organization in this process.

Things that -- you're not going to learn anything when FDA comes in and they're going to give you a list of what's wrong in your 482 you're not going to learn anything from that process. It's very different engaging with CMMI because they come in as a consultant.

So not only are you going to be getting feedback on what you're doing, but you'll be getting information about how to address some of those concerns. And that is why the agency is not looking at the details. We're not looking at all of the

pieces of your heat map. We just want to know overall how you're doing at this stage and that's the feedback and we're asking for.

We want to review and approve any significant changes of direction and scope. If we get into the pilot and we find out that we need to make some sort of modification the pilot governance committee or governance board will be able to work with the various people who are participating in the pilot to achieve that.

And then, frankly, address any kind of appeals or, again, issue with program de-enrollment. If someone needs to off ramp or whatever then make that a smooth and easier transition if possible.

And then finally over time hopefully identify what the operational governance requirements are going to be. The goal is to create a much more robust, sustainable future with this model. So the governance committee will be looking at this on an ongoing basis to identify the elements of what that sustainabil- -- sustainable program looks like.

So I'm not going to spend a lot of time on

this slide. This is just basically roles and responsibilities between the FDA, MDIC steering committee, and CMMI. So you can take a look at this on your own time and you'll be able to kind of read through it.

Recognizing that we're looking in general for the agency will always do what the agency does. So we do have a compliance role, we do have an enforcement role. And in situations where there is a need for that we will continue to be the FDA.

But hopefully in this -- for companies participating in the pilot because of the fact that we have open and transparent communication things will be identified very early so that they don't become big issues that the FDA has to come in and do anything, any significant enforcement action around.

So the steering committee, itself, will be looking at the pilot progress, the trending, communicating with industry working through that. And then CMMI overseeing the appraisal process, the continue development of appraisers.

It's my understanding -- and, Cisco, perhaps

you can clarify -- but the people that are working on the CMMI will actually have some medical device training and background. Yes. I see Kim shaking her head.

So these are not -- even maybe -- it's not like a situation where with the Food and Drug Administration where you -- the guy that's coming in to audit you is in a fish factory yesterday. These people will actually have some medical device background and, of course, the new FDA is like that now, too.

But they will -- they will have a medical device background and they will know your industry. So this is not, you know, someone who only knows something about software or only knows something about aerospace. They will know something about medical devices.

So a little bit on why maturity. The -- when we look at an organization you think about what the concept of continuous quality improvement implies. It improves the ability to be a self-learning, self-correcting organization.

Well, that is not something you're born knowing how to do. And someone mentioned small companies, they may not have a lot of sophistication or a lot of experience around it.

That's why focusing on maturity is a very intriguing option because what it tells us is that you are able to learn from your mistakes, you are able as an organization to grow and modify based on experience, to adapt to situations in a proactive and -- and I think really almost premeditated way so that it becomes part of the culture of how you work and how you think. That's why maturity is truly I think a very, very important and powerful of looking at your quality capabilities.

We're going to provide guidance on how to drive and prioritize improvements and deliver value on your business objectives. One of the things that you might think about is when you -- if you were an organization engaged with CMMI on a big scale you talk about the score you may decide that 50 percent is GE in some particular category for you from a business perspective because that's not part of your core

business or it's not really something that drives product quality in any way.

This is about your business decisions. And someone talked about what do we do with these data? These data are your data so how these data are used by the company is up to the company. So that's important.

I want to emphasize that because the agency's going to be looking at some slice of this as you saw, just the final scores. But how you use these data for your own organization, how you communicate them internally to your board of directors, to your stakeholders, et cetera, is really up to you to a large extent.

We want to provide guidance, then, on how to pri- -- how to prioritize improvements. And that's where the CMMI consulting team is I think very, very powerful here because one of the challenges we have now is is you were to get a 483 in a classic audit symbol how much feedback do you get from FDA on how to respond to your 483?

I see a lot of heads going. That's right.

But this is a very different thing that's why I said this is not an audit. So this is -- this is an assessment and it's an assessment done in partnership with a capable assessor. So that's very different model.

And they don't have the regulatory prohibitions that we have as an agency in terms of the way they interface to you so very powerful I think. And the opportunity I think to provide great business insight to you as an organization.

We want to enhance confidence, trust, and transparency. Remember back to my word of trustworthiness. The more we can create an environment that encourages that trustworthy relationship both on the part of the agency as well as the part of our industry counterparts the better it is for patients.

Because if we are highly trustworthy, you can count on us, you can depend on us, if we're reliable, consistent, et cetera, in what we do that's good for you. And if you are the same way in terms of the way you create your products, improve your

processes, make your company a better company that's good for patients and that's good for providers. So this is a win-win for everyone. And trustworthiness is at the base of all of that.

And then finally, again, we want to get to that point where we're not your mortal enemy. We actually never were. It felt like that sometimes, but no. And we're not your best friend although we do like you.

But this is really about -- this is about that relationship between a regulator and between a regulated industry that says we can be trusted colleagues. You can count on us to be consistent and we can count on you to deliver what you're supposed to deliver. So that's where we're trying to go with this.

So a little bit about the pilot goals. You heard about the basic steps and I think you guys did a great job of explaining the steps for this. But what is the reason for it?

One of the things we want to understand is scalability. We think that this model is pretty

infinitely scalable. And some- -- if somebody mentioned small companies versus large companies. We could even imagine that a small company that's actually highly focused on just one or two products this might actually be more robust. It might even be easier for them to get a lot out of this than it would be for a larger organization.

I would certainly tell you if you were in that space where, you know, you wanted to be acquired or something like this, this could be a very powerful tool for you from a business perspective if you're doing well in this space. So consider that.

But we want to understand the scalability of the model. We hope to be able to get that information from the pilot.

Obviously we're going to evaluate the pilot program, decide if we're doing it correctly, how much data do FDA really -- does the FDA really need. I mean, right now we're just talking about just getting the scorecard on the end. I don't know yet if that's going to be enough information for us to have the confidence that we need, but we're going to start with

that and see how that goes.

And that may not be all we get. We may find that there are other types of information that a company could proactively feed to us. Like one of the things I talk about a lot in the Office of Compliance and I know from all my years in industry is companies have a lot of information that is never shared with the Food and Drug Administration that's actually valuable information in terms of understanding your company's capabilities.

Maybe there's something else in addition to the CMMI-type data that might could -- we might identify in a process of this pilot that would also help raise the trustworthiness level and create that confidence that we're looking for.

And then we want to look to evaluate the pilot to figure out how we can improve our efforts and increase efficiency so that as we roll into a full integrated program in the future we will have learned what we need to learn from the pilot process.

We're obviously going to try to work on some metrics. Right now we have, as you saw, some idea of

what kind of metrics. And every company creates the same kind of metrics, you know, time -- whatever it is whether it's time to cap a closure which is actually terrible metric by the way, but there are lots of -- lots of types of metrics that we collect and that may or may not be meaningful in this process.

And so the important thing is to identify what would be meaningful and how can that information be used in order to, again, increase confidence and raise trustworthiness.

From an FDA perspective we're looking to improve our inspection resources and to improve the use of those resources. We have a finite number of resources available to us and it doesn't look like we're going to get a whole lot more.

So the important thing is we want to use those resources where they make the most impact on public health outcomes. So the idea of just routinely, you know, going out to do an audit for a company that's actually doing quite well and has been doing quite well and is scoring well on the CMMI is that is probably not the best utilization of the

agency's limited resources.

It would be much better to go out and use those resources in areas where situations are not under control. So we want to be aware of that.

We want to make sure that we improve the visibility to industry trends not only to ourselves, but across the industry. So that has to do with how we disseminate information.

And to identify the high-performing firms and find a way to reward those firms for that commitment to high performance and high quality. Reward them by lowering their regulatory burden and trying to find the least burdensome way in order for them to demonstrate that they are a trustworthy, capable organization.

From an industry perspective I'm sure you want better utilization of your resources, as well. Having 35 people sitting in a back room with six printers and a bunch of, you know, screens on the wall how good is that?

So the idea is that that may not be the best use of your resources either and it may not actually

create the value for you that we would like to see it create. So we're trying to do that.

Improve your quality culture. Can't say enough about that and don't have enough time to say everything I want to say. But quality does start from the very top of the organization all the way through. It has to be part of the very fabric of who you are.

And participating in this assessment and these kind of ongoing pulse checks you've been hearing about is one of the ways that you as an organization I think can create that.

And then, frankly, we want to reduce the amount of disruption. You mention MDSAP. MDSAP does that because it decreases the amount of audits. What if we could decrease those amount of audits even further in some way through some other -- or amount of regulatory activity anyway through some other mechanisms. And that's what we're looking to do.

Sorry. The most important thing is in the process of all of this we need to have a learning mindset. So both the agency as well as industry, our payers and providers and our patient population

learning together, figuring out together what is meaningful, what has the health impact we're looking for, how do we really improve the lives of patients, and how do we really improve the interaction that we have with those stakeholder groups. That's what we're looking for. Figure out what works well, what needs to be improved, and focus on adaptation and communication.

So I have a couple of minutes it looks like left so if we have any questions I'll take those.

MALE SPEAKER: Robin, as part of this learning process obviously as the pilot is going on it's going to take some time with companies getting involved, going through at least one cycle and probably cycles, how long do you see this pilot program lasting?

MS. NEWMAN: You know, I knew you were going to ask that question. It's going -- it will probably take a while. I mean, certainly the first six months we're just ramping up and not everybody will ramp up at the same time. So I could -- I would anticipate, you know, the primary -- the guts of the pilot try to

get through the first year and then we'll have to assess what we're going to do at that point in time. But right now it's scoped for a year.

Anything else? I stunned you into silence. Okay. One more.

MALE SPEAKER: I just have a question. If the primary interest is in learning how the organizations are doing, are you also collecting qualitative information in addition to the kind of final score? Because that final score may hide what's going on underneath and not allow you to see what's happening qualitatively to the organization.

MS. NEWMAN: It's a great question and I will tell you -- admit that I am not a CMMI expert. But any time you're in an auditing mode or an assessment mode where you're doing a lot of interviewing you are getting -- you are gathering qualitative information.

Now how that's used in the CMMI model I'm not quite certain. Perhaps one of my CMMI colleagues could tell you. But it certainly speaks to culture. And culture of an organization also has a very

qualitative component to it.

MALE SPEAKER: So certainly within CMMI appraisals we collect a certain amount of qualitative data that ties to the capabilities of an organization. And we've -- we also indicated on that slide that organizations can -- in defining their objectives for an appraisal it's often common if the executive sponsor says, hey, look, since I understand this is an event that gives a lens into the organization I'd like to also have you look at these particular areas.

Common way an executive sponsor might do that would be, you know, we call it the two questions. Hey, if you were to start this organization over what particular processes or what aspects of this organization would you continue to leverage and what aspects would you absolutely get rid of?

So you -- and that's a very direct way that sometimes a sponsor and appraisal will get right to those qualitative aspects for their organization to provide business value, add for them as to what things they'd want to work on or what they would like to keep.

So there's both aspects within the model that specifically get to those sorts of qualitative pieces, but then there's also flexibility within the appraisal to extend it to meet the needs of the organization.

MALE SPEAKER: Thank you.

MS. NEWMAN: Okay. This is the last question.

MALE SPEAKER: What's the plan -- what's the planning process for translating this pilot program into a full program assuming that it's going to be successful? When will that planning occur, who will participate it, and how will there be opportunities for stakeholder input?

MS. NEWMAN: Well, thank you, Steve. I think that's going to be a great segue into Sean and Cisco's talk. But to the point that's one of the -- that's what the steering committee -- that's one of their primary charges is to assist with that.

Okay, everyone. Thank you so much.

MR. VINCENTY: Okay. So one of the things that I think we -- that we constantly get asked is,

you know, what does it take to participate, how do you -- what is the expectation from the company, how do you get enrolled or the other way, you know, how do you get booted off the program?

You know, the gentleman here in the formal, you know, military suit I'm going to have him come up and really present the rules now.

MR. BOYD: Good morning again, everybody. It is maybe no mistake that they gave the rules presentation to the guy in uniform. So what I'm going to cover over the course of the next 20 minutes or so are the participation criteria and rules of engagement for the program that have been defined.

I'll talk about, again, the criteria for enrollment and participation of pilot participants, we'll discuss some pilot goals and logistics, we'll talk about the engagement model and the interactions that FDA intends to have with industry members that are participating in the pilot and the commitments that we hope to get from both the participants and we intend to make ourselves.

So with respect to enrollment criteria,

while the CMMI maturity model is scalable from one to many sites, we also know that each medical device manufacturing site and sometimes even unites within the sites can have different cultures and different challenges that might need to be addressed.

For this reason as part of the pilot we expect that firms will enroll and appraisals will be conducted specific to a single manufacturing site. This includes sites that manufacture finished medical devices and contract manufacturers such as a site that performs sterilization.

In fact, we're trying to exercise or incorporate a variety of firms within the pilot so that we can learn from the experience and see how well the model applies to firms of different size using different manufacturing practices and processes within the sites to evaluate the robustness of the model, itself.

The pilots also intend to evaluate a different engagement paradigm with site participants. And while we think there's a lot of potential for this model, for a new firm or a firm that may be struggling

with meeting that compliance baseline expectation those sites are out of scope of the pilot right now.

For the pilot we expect that participating sites will have demonstrated compliance either through their most recent FDA inspection or their MDSAP site audit within the past five years and really have a clean compliance record. Meaning that the last FDA inspection was either NAI or VAI and MDSAP only identifies -- or the MDSAP only identifies minor non-compliances.

So and, again, a maturity model does not establish your firm's quality system. Rather the model is an appraisal that evaluates how capable your system is and what level it's performing at. The recent compliance inspection or audit ensures that pilot participants have met that basic compliance expectation.

In order to enroll in the pilot you can go to this address on screen as has been provided previously and kind of fill in details of the enrollment form that pops up.

Jennifer, could you click on the eligibility

criteria image? Not that. The elig- -- right there. Oh, actually my animation is not here. Go back one or I got it.

So I was just going to give you a brief tour of what the CMMI and MDIC enrollment form look like, but you can do that at your own leisure and I will hold the extra time that I've got now for questions.

We expect that you'll have questions over the course of the pilot leading up to the pilot and after you've been participating in any appraisals you've already gone through. So there are multiple different ways you can reach out to folks that have been coordinating the program in order to get additional information. And these are the contact points that you can reach out to.

So with respect to participation expectations, as discussed by George previously we expect that the appraisal will take place within 90 days of acceptance into the program. Acknowledging that there may be reasons that we would adjust this either based on available resources through CMMI or the firm readiness for a particular audit and we will

make efforts to adjust that timeline as appropriate.

The pilot is really made to assess all aspects of the program including scheduling the audit. So this is something that we will want to gather feedback on, as well.

Additionally, the pilot will assess how we can use objective metrics as a means of monitoring process -- or progress which, as has been discussed, will be tailored to each individual facility within the pilot based on the volume and type of products manufactured, the services provided by that particular firm, and the tools that they have in place to assess and measure progress and performance.

Additionally, there will be some questions and surveys that are used to measure the appraisal process, itself, and how the pilot program is going. And the teams that were described previously have worked to not add significant burden, but this is another important aspect that we need to assess through the pilot program. And we need your participation in providing that feedback to us, as well.

Additionally, participants will provide updates to their metrics in the process area checks that establish time intervals which were described ranging anywhere between every 90 and 180 days.

We're really looking to provide or work to make this non-disruptive and looking to assess how we can use this information in place of additional audits or how this can really help us assess how a firm is improving with respect to its performance over time.

And lastly, we expect that participants will be willing to engage early and provide candid feedback on all aspects of the pilot, itself. We, as FDA, intend to learn and adapt with the governance structure that has been provided based on your feedback about what's working and what's not.

And we want this openness and transparency really to make sure that we address any issues quickly and incorporate your feedback over the course of the year that the pilot will be ongoing.

In terms of pilot program logistics we have a goal of enrolling a minimum of 30 sites over the duration of the pilot which will also be appraised

over the course of 2018. Due to the level of interest that's been expressed in the program to date we fully expect we will meet that goal.

To answer the question, the pilot will run between January 2018, or once it's announced, through the end of 2018. And given the 90-day window for scheduling appraisals we plan to stop new enrollments in the pilot about 90 days prior to the end of the year to allow time for that appraisal to be scheduled and conducted by the end of the pilot period.

There have been questions regarding what information will be provided publicly to describe the appraisal process and other aspects of the pilot. We will be continuing to build additional information on those details including templates, modifications, and what learning we're experiencing over the course of the pilot that will either be available on FDA's Case for Quality website or through MDIC or CMMI.

The cadence of kind of when this information will be available and when it will be made public is still in the works right now.

And then with respect to feedback for the

pilot program I shared this morning there's about ten days left to comment on the open public docket regarding the previous Federal Register notice which you can also provide additional comment based on what you're hearing today.

We'll also be reopening the docket in the next week or so in order to gather feedback for an additional 45 days following this meeting in order to gather some additional feedback based on what people are hearing over the course of today's meeting.

After this feedback will be collated and evaluated internally with kind of a summary assessment provided at some point down the road.

So with respect to engagement and interactions, a key part of this pilot is developing strategies for how we address product quality and safety issues as they occur.

FDA will be focused on identifying these issues early in the process as well as responsiveness, containment, and resolution. And we're looking to provide approaches that we work with industry to provide the best results, improve your internal

processes, and learn ourselves from how we can modify our interactive approaches through this engagement.

So product quality issues are going to happen. We fully expect that over the course of the pilot program with participants in the -- participating in the maturity appraisals.

In these situations where issues have not escaped your firm's control CDRH expects that your quality system will manage them in the fastest way possible. And we're interested in learning how well your system responds to identify these and resolving them as part of the information that we collect through interactions with you during the pilot.

Our goal is that you identify more issues using more sources of data that you have available to you internally early in the process and are resolving them early using driving improvements that increase visibility and responsiveness so that you're more proactively identifying and addressing potential future events.

Again, we're in a learning mode during the pilot and we're interested in interacting with you on

what these -- what your internal practices are so that we can determine how we might modify our regulatory approaches accordingly.

Additionally, we expect that public health and safety issues will occur during the pilot with participants, as well. As you identify these product defects for devices that are in distribution or you learn about an issue where you're -- and your -- that's introducing a hazard with your product or causing a potential patient safety issue what we're looking to see is rapid containment and resolution of those issues through your firm's efforts.

Again, we're looking for early engagement with you in these situations, as well. And would like to learn from the event to identify potential ways that we can prevent future problems from occurring.

Additionally, we'll be looking to identify areas of improvement for your internal resolution processes and identifying opportunities to share that learning not only within your -- within your facility, but share those best practices across industry on the whole.

We're not looking to rely only on compliance and enforcement solutions or tools when addressing these issues; however, as has been discussed, our kind of regulator/regulated industry relationship kind of must be maintained. And there will be certain reports of events that you would have to submit. It's the approach that we use in follow up to submission of that information that we'll be modifying.

Really our goal is to reduce risk and improve patient outcomes through these interactions. So we're committed to engaging a little bit differently or differently in order to drive toward better results sooner. It will be based on a commitment to transparency and taking early action when issues are identified.

We will commit to meeting with pilot participants and discussing potential issues surrounding the event that occurred or the defect that's out there and working with you to develop resolutions that achieve patient safety and product quality.

We expect that firms will develop robust

action plans that will be followed up on with clear timelines and deliverables to ensure that issues are addressed.

And when we discover instances where issues have not been communicated or there's no action or a lack of commitment on the firm's part to address issues that have been identified we will look to kind of revert back toward our traditional compliance and enforcement options as opposed to these interaction approaches.

So in summary, the commitments that we're making and we expect pilot participants to make with us is to develop this learning system and really be open to continuous feedback and engagement over the course of the pilot.

We are focused on product quality and patient safety first. And the best or most rapid path toward achieving that are the options or solutions that we'll pursue through this pilot.

We also want to adapt and learn from the feedback that you provide whether it's regarding an aspect of the pilot, itself, or aspects of the

maturity appraisal process or other things that we can really adapt and improve the pilot over the course of the year that it will be ongoing.

We also intend to incorporate least burdensome principles into all activities that the center pursues particularly focused on how we can incorporate that with this pilot, as well.

As has been discussed by previous presenters, the metrics and the data gathered are going to be used for learning and understanding how new and different data can form -- inform FDA decisions and not take that information and turn it into a compliance or enforcement action.

We are committed to implementing these solution-focused approaches so long as we can maintain and kind of built this new relationship with industry and engage on more interactive, collaborative solutions toward identify issues and resolving them with you.

So with that I think I've got plenty of time for questions or actually a couple minutes. Luann?

MS. PENDY: Good morning, Sean.

MR. BOYD: Good morning.

MS. PENDY: I'm Luann Pendy from Medtronic. And you know I'm all in for the program so I'm not -- this is not a criticism. But I saw on your slide that you said that it's the sites with good compliance history and going back five years NAI/VAI. I don't know if it's four years or five years. That doesn't matter.

That almost seems as if it's cruel and unusual punishment because it's those sites who have worked very hard to become compliant to improve their quality program that I would most like to see the CMMI assessment on to see have they actually done the things that they said that they were going to do and have they made the improvements so that they are as mature as everyone else.

So I understand maybe in the pilot you don't want to maybe muddy the waters with some sites like that, but I would just encourage all of us to think of it in a positive way, the positive reinforcement of a site that was in a bad place and now is in a good place and gets the reward of being said to be

compliant and mature.

MR. BOYD: Yeah. No. I think that's a great point. And, I mean, certainly we agree with you I think from the pilot program perspective. One of the things that we need to rapidly assess is are we certain that firms participating have met that compliance baseline?

And I think over time one of the goals that we have -- and I don't know if we're presenting the kind of four or five year slide today, but we are looking for ways of opening the door and incorporating or allowing participation of those new firms that have an undetermined compliance history or that they just simply haven't had an inspection or audit.

And identifying the firm that has had challenges in the past so that they can get in early on this appraisal process and identify what are the steps that they need to take and where should they focus in order to get on that path to continuous improvement.

And there's no prohibition from a firm engaging CMMI I think in that way outside the scope of

the pilot. And this is certainly feedback that we would want to hear from participants early and often in the process if you see a lot of value here. Yes?

MR. ROBINSON: Good morning. Hi. Dave Robinson from Proctor and Gamble. We met at Xavier MedCon.

MR. BOYD: I remember, yes.

MR. ROBINSON: Yes. Yes. So my question is you mentioned that there would be a baseline set of effective metrics that would be submitted from the companies that participate.

Are those baseline metrics available to all as part of a pre-enrollment type of situation and can you speak to that?

MR. BOYD: Right. I think CMMI spoke to this briefly. The baseline metrics are going to be tailored to the specific firm and the specific products and the specific goals that the firm is trying to achieve.

So I think there are elements that will be common across participating firms, but they're really intended to be tailored. I see Cisco has stood up to

kind of provide some additional detail on that.

MR. VINCENTY: Yeah. So in addition to that as part of all the documents that we'll be sharing online we'll be putting up what we've got in draft form, here's what we're looking at, here's why, what those metrics and what that template might look like.

And then you'll get further engagement and more details when CMMI and during any scoping discussions. But you'll be able to see ahead of time what we're looking at and why we're willing to look at those.

FEMALE SPEAKER: Good morning. You had talked about the rules of engagement regarding the exit of the pilot program. I'm curious has there been any discussion regarding how to maybe re-enter the program maybe not as part of the pilot, but longer term?

MR. BOYD: I don't know if the groups have discussed reentry specifically, but, I mean, again, I think that is something that's feedback that we would want to receive if there's been an instance where a firm entered the program but we didn't see a

commitment to communicating early with us or we didn't see successful implementation of -- or fulfillment of the commitments that they made with respect to following through and identifying how they were going to address issues as they resolve -- or as they arise.

I think that's an important conversation for the groups to have is to identify when and how a firm might get back engaged into the pilot if that occurs.

MR. VINCENTY: It's one of the -- so right now the mechanism we're providing is through the pilot steering committee kind of appeal activity. But we want to be able to craft out and formalize it a bit more if it goes into more operational states.

The one thing to remember, I mean, you've seen a lot of what the approach offers, right, you've got time. This is -- we're not approaching this from the standpoint of, you know, enforcement issues. We want the early engagement. We're committing to these other kind of interactions. We want to get to the resolution first.

It really is going to take a lot of more purposeful incentive action to be really kicked off

the list, right. It's part of that growth that we want to be able to evaluate or else the program really isn't delivering the value we need.

So just to put that in perspective somebody has to really try to get disenrolled.

MR. MCKEAN: Thanks, Captain Boyd. Great presentation and program. Matt McKean (phonetic), Boston Scientific. You'd mentioned a minimum of 30 companies and you anticipate a lot of enrollment and activity and hitting that number and beyond.

Are you just going to go with sort of the natural random distribution of companies that apply or are you going to like label small, medium, large just to get a sense for it's not all just the big companies?

MR. BOYD: Yeah. So I think the plan is to take all comers over the first nine months of 2018 in terms of open enrollment. But we will want to capture demographics that you described on the particular firm whether it's the size of the firm itself, the types of products it makes, as well as other information so that we're getting whether it's a contract

manufacturer or finished device manufacture so that we're getting -- we understand what that demographic is for pilot participants so we see how applicable the results can be to the entire medical device industry.

But we're not kind of limiting participation based on any of those subgroups.

FEMALE SPEAKER: I'm Joan from Instant Systems. I understand you indicated that the pilot program the metrics will be tailored specifically for the type of facility.

But what if a company is in the process of expanding and are registered -- they have one facility, small company, they're registered in a program and three months down the line or two months from now they're expected to be expanding?

How would that impact their enrollment? Would they be enrolled as a company as a whole or would they be enrolled as that particular location only?

MR. BOYD: So the enrollment is specific to an individual site --

FEMALE SPEAKER: Site, okay.

MR. BOYD: -- for an individual facility.

FEMALE SPEAKER: So while they're enrolled on that first particular site is there -- is there a -- an opportunity for them to add into the site?

Because currently at the moment our company is an R and D and development and manufacturing. And two months down the line we're going to have another bigger facility where we -- our quality is actually collaborative.

So how would that be --

MR. ZACK: So with any of our -- with any our scoping and scheduling conversations every one of these device manufacturers here is unique whether they're one device at a single facility, 50 devices, whether they have hundreds of facilities domestically, internationally.

And in this case your organization is unique, as well, and that's part of that scoping conversation to make a determination as to what make sense. For the point in time appraisal does it make sense to say we're going to look at where you are with your organization right now or do we have a

conversation with the agency to say it makes a little bit more sense to hold off on -- great, you're enrolling and but it makes sense to hold off on this appraisal or maybe even perform two appraisals or whatever it is to appropriately consider the scope of your organization and also to determine where the regulatory modifications should line up, as well.

FEMALE SPEAKER: Okay.

MR. ZACK: So it's really that -- it's that scoping and scheduling conversation where those sorts of things get figured out.

FEMALE SPEAKER: Okay. Thank you.

MR. BOYD: All right. Well, thank you, everybody, for you attention thus far. We're going to take a ten-minute break. So on my watch I've got 10:40 so please return at 10:50 so we can resume our morning program.

(Brief recess.)

MR. VINCENTY: So this is good because, you know, I like to have Sean go and give the rules before then I go back and talk about what are some of the possible benefit incentives that we're looking for.

It makes me feel a lot better like I'm giving away more in that end.

So let's see, okay. We're going to go through what are the pilot modifications, right? We are looking to leverage this not just for, you know, the benefits that it brings from the CMMI standpoint, but really what is the additional elements that we can gain from an agency.

And if that gain actually provides a value I think everybody gets a -- it's a win-win situation for everyone.

You know, go over why we're doing those. You know, what does it really mean? I know what's it going to look like possible an example we've got set up here. And then what happens after the pilot because I've gotten that question significantly, right.

We got through this, these modifications come into play while we're in the pilot, what happens afterwards?

So one of the pilot modifications that we're looking at is, you know, really focused around the

inspections. You've heard some of that already to begin with, you've heard what we're looking to do from our surveillance standpoint.

PMA original manufacturing sections what we're trying to consider there and what we're looking to do. Site changes, how we're looking at them a little differently and what that means. And then the 30-day notice change which is giving us, you know, the biggest example right now of what we're looking to try to pursue on our end.

So let's talk about the modifications for the inspections. I think you've already heard the big benefit, right? The site gets removed from the routine inspection work plan. But that's not the only real benefit that goes on with this, right.

As you've seen, the appraisal process it's not a situation where we're coming in to surprise. We're not coming in to catch you doing something or not doing something from a compliance standpoint.

You've got time. They're coming in, they're working with you to tell you here's what's going on. Let's plan this so that you've got the people

available so that we could really have some active discussions. This is really meant to me exactly that, a discussion.

This is something that I think we've heard before people just even had a few notice -- a few weeks of notice to prepare to have the right people available. That kind of makes all the difference in the world for even a normal audit.

So in this mindset you've already got that engagement. You've got the scope that you're contributing to. They come in understanding your business objectives and then they go in really trying to engage openly to figure out, okay, is it really -- everything you've put together, all this work that you've, established, is it delivering for you especially along those objectives.

And if it's not where can it improve? And if it's -- if that improvements needed here's where we've seen it done well or here's how it applies well for the specific level that you're at. So from that standpoint we are taking the sites off of our risk-based work plan.

And then we're going to use the appraisal checkpoints, right, just to make sure progress is going especially through the course of the pilot. If things operationalize down the road we will revisit how that gets looked at, what we do.

I think Steve commented and he came up to the microphone and asked, you know, if we go into operational -- operationalizing this program is there going to be opportunities for feedback, is there going to be more engagement around that.

And our goal is really to try to make this as transparent as possible. We want to put this up for viewing whenever we're changing our thinking, when we think we want to adjust.

If we start going into operational modes, that'll be made available and it's got to be made public. There will be more opportunities for feedback.

We've provided avenues for additional feedback emails. We're encouraging it. We do not build something like this without that engagement so please keep that in perspective.

So when does that benefit kick in? It starts one the site is accepted, right. Once you've been selected for that enrollment activity we've done our verification for the criteria, you get your notice, we move you off or our risk-based work plan and our surveillance work plan.

That -- you know, again, bear with us. We're in a learning process so if anything happens please give us a call and we'll try to work out what's actually going on.

This does not actually take the place of, as was mentioned before, having a RAD health inspection or a drug inspection if you're doing that at your facility. If there is a pattern of things going on and there's a need for direct inspection, that's still something that may be possible.

So we're looking to make sure we're lift -- we're moving in this direction, but if there is some signal or something else that we've got to react and respond to that's still something that's under our regulatory obligations that we've got to do.

Okay. So why are we doing it? Sean

mentioned it. The model isn't there to tell you what your quality system is. It's there to tell you how well is it doing its job, how well is it delivering for you, at what level, where are its opportunities for improvement.

For this pilot we chose specifically to have at least firms who have demonstrated compliance in the past five years because we want to eliminate that extra set of variables, right. What we want to do is make sure that the pilot is actually moving beyond that compliance basepoint that the appraisal moves us in that direction before introducing, okay, now how can the appraisal help with these other ones.

We want to look and see and evaluate can we drive that improvement in the system. If we focus on that improvement, if we focus on the idea of how is the evidence generated that shows that all these systems are playing together, you know, away from just I wrote up a document that says here's how we're going to do this.

We can then take that, apply it, and then learn from that one for maybe other adjustments that

need to happen on the road or that have the potential to happen or, as we talked about, how does it apply for the innovate space for the companies that need the help most.

We know that the inspection process -- we've heard this, this is some of the feedback we've collected. It's one of the reasons why I like the engagement that we get through MDIC. It's open. It's disruptive. We got it. We heard that.

So here's an opportunity, again, staged, planned, not looking for what's wrong. We are looking to start with what is it that you are currently performing at and let's move from there. So we are moving -- once we've got people enrolled this is the shift that we're looking to make with you.

From our standpoint we do, we receive more robust and objective data. The granularity even with the shaded business process areas that we get still provides a lot more insight into what the performance is like at a manufacturer and where it's starting -- where it's starting point is and where its opportunities for improvement are.

The other piece of this, and it's been talked about a couple of times, is what are these additional metrics, these effectiveness ones that we're looking to collect as we go along the way?

The goal of those is really to start looking at how are you identifying issues, at what stages, and how are you responding to them and that's really what it is. It's very simple aggregated numbers with an idea of where your sources are.

The -- it was mentioned beforehand, right, that it is very personal to that site and what's going on there. But there actually is opportunities to benchmark across the board. When we see high performing firms then we recognize maybe they're incorporating extra sources of information that other ones aren't, that's something we can make available. Here's what we learned. Here's what other people are looking at who are performing better.

Firms are you actually identifying issues and resolving them earlier in the design cycle we might be able to get that or we might see that there is a bump or an increase in issues after the fact and

that's okay. That may be something that we can now explore is that because of an issue that was unanticipated? Is that because they introduced a new product to market and that's something that might happen.

But now as an agency we've got more visibility as to really what that kind of performance looks like and how we can respond to that in order to actually move the needle in one direction or another.

So we're looking at now what we are proposing for our PMA manufacturing sections. So we want to streamline that submission. We really are looking to move back into the cycle -- the idea of a systemic look at things. And that's where the transparency that we gain from the appraisal moves us.

We want to have something, you know, a short notice that you're participating in the pilot because we've got to discern that from all the other ones that are coming in normally.

We are looking -- there are certain product specific records. The other piece of all this that I don't think we've covered yet is that we are really

looking to establish and do all the pilot activities within what is required of the regs and the act so that we're not looking to modify anything in law just yet.

So within that submission activity, you know, there is something that's related to the product then we will be putting out a template of what that might look like, the design plan. And then there would be a sampling of the supporting documents only for critical processes. Not everything that gets submitted now.

We don't want be revisiting your SOPs and what's been developed. That's not part of the submission anymore or part of the review. And then we are looking to waive the preapproval inspection. Again, benefit there. We are learning from what the appraisal is delivering for us and the additional checkpoints that we're getting.

You're taking a leap of faith with some of that stuff. I think there are some elements here where we can take and meet you halfway and say, hey, we believe also that this is going to give us a

better, more robust set of information and visibility into what's happening. This is something that we can give on our end.

So as mentioned, once we get that benchmark data and that summary data we can start moving into this form of operation for the manufacturer because at least now we've got our starting point to really look and check against.

I mentioned it already. We want to be moving away from that product-specific discussion for any of the manufacturing that's happening at the facility. We're getting increased transparency and confidence into your system so it's something that I think alleviates a lot of the concerns from our end.

Sean mentioned one of the key factors that I think will help with all of this is that engagement and that communication, right. We don't want surprises. This gives us a little bit more of an early look into what's really happening and what's the capability of the system there.

It accelerates the approval. We mentioned the idea that patients are really the primary focus.

Why can't we get the product of a manufacturer who's performing, who's open, who's transparent, who's willing to engage in quality practice out there to the patients faster?

And then the last one least burdensome, right? Not just from you, from your standpoint, but really from our standpoint. How do we reduce the focus on generating artifacts just to submit in some cases, you know, where we might not have all the resources and time to look at them all fully?

So how do we get smarter and better about that? And this pilot lets us exercise a proposal around that element.

Site changes. Very streamline submission here. Again, participation of pilot. All of the elements that we'd normally be looking for when that site change is happening we've probably already assessed through the appraisal and we're getting these checkpoint elements on.

We're looking to move more into a mode of some structured data that we could trend over time. So we're going to identify here are some key things

that we'd like to see. If you can provide that table format, maybe a sampling of, again, those critical processes to make sure everything's there. Can we accelerate the approval?

Now I put in a target of a week for our end and we're going to exercise if that's even doable. You know, we might do that and see if we can get through that process very quickly. We might learn, okay, we can't get through that approval that quickly. There's still a lot of review and it may be resource driven, but that's something that we can -- we can really explore through the pilot and put out there.

Again, once the benchmark is completed that's really where our key point starts. We have at least a baseline to move from.

So the approval it's giving us that system capability assurance. So if you're looking at a site that has already been evaluated in this fashion and you want to move product to that site we've got confidence that your system can manage and handle that move. And then there's extra visibility into what may result as part of that transfer process.

You know, it does really accelerate that movement for manufacturing sites. And, again, we're going back to the least burdensome principles.

30-day notices. This is where we've learned a lot during our engagement. This is where we really I think had a big ah-ha moment, an eye opening experience from all the engagements that we've had with manufacturers.

It's very different thinking on this side that the manufacturers only -- is actually making the changes and submitting what's going on. But I don't think we ever realized the impact of the submission, the process, the delay that it causes the need for prioritizing regulatory resources to even accommodate 30-day notices.

This is really a mechanism that was intended to help at least give us awareness, but now it's turning into something that's kind of preventing that rapid innovation, that rapid improvement that's happening at a manu- -- that can happen at a manufacturer.

So how do we get that started again? How do

we get that process going in a safe way so that both the patients can benefit, you can optimize, you can get a better product out there and we probably can get a better set of data from our end?

So we're looking at very, very streamlined submission for the 30-day notices. Participation of the pilot, so again we can bring it out. We are moving to a structured data set for the submission.

We will put some of that out there. I'll present what we're thinking in a little bit just from the data standpoint. We've got rough template we've developed to kind of show at least what's going on. Does it need to be stuck to that template? We're open to any thoughts, ideas, or other input on that piece.

You can currently bundle changes across submissions and products. We're going to also incorporate allowing more changes in the submission. And then the big key part is we're trusting the system and we're trying to develop a way to go back and verify versus having to review all the elements ahead of time and then move forward.

So we are looking to deliver that acceptance

of that submission within that 24-hour time frame so that you can implement the change and start distributing quickly.

Okay. So we do get increased transparency. The structure data elements that we're looking to define actually give us a little better visibility as to what's happening at a manufacturer than I think what we do now when we look through the full submission package.

It does accelerate the approval and the capability for improvement. Again, moving away from the artifact generation. We're looking for evidence, not documents. We've got to really figure out how to shift that mindset here and that's -- there's multiple ways of doing that.

Taking a step into the way -- into just setting up the structure to look at things from a data analytic standpoint and more of a trending standpoint is where we're looking to take some steps in with this -- with this part of the pilot.

So let's see what we're thinking. And, again, I put out a pilot just for some early feedback.

Got some great feedback. You know, some stuff that people were very confused about, got it. We're going to try to put this out there.

But here's the things that we're looking for, right. Some key elements to submit, but what are the structured data fields?

Well, your change order number. That's our traceability back to your data. Your system already does that for us so why are we getting an extra copy of it? So if we have questions we have a way to engage with you and figure out what was done and performed at that stage.

The effective submissions. What was the type of change? And this one we'd like to kind of categorize into more of a drop down field so we could say, okay, here's the types of changes that are happening. We could trend that a little better over time. We could see a manufacturer who's maybe in certain submission areas incorporating a lot of, you know, maybe cost improvement changes.

Well, we can engage, we could learn with what CMMI's appraisal was and maybe find out, hey,

that's already a mature product or they're already at that mature state. All they're looking right now to do is drive cost improvements, gain value. That's a different perspective I think than what we have right now.

We can also engage and say, oh, there's another one that's got a lot of, you know, quality changes that they're making right up front. But it's a new product that they introduced, that's expected.

That tempers our response. So we've got to figure out, you know, again, this is all part of the learning. What does this tell us? How do we start leveraging all these data sources together in making better decisions off of the elements that we're getting from the actual submissions?

So if we're asking for this let's figure out a better way to use this. You know, the device -- devices are affected, the FEIs that are impacted. We're going to try to really put together not just a template, but a data dictionary of what we're looking for in terms of elements, what we mean when we talk about that specific field. That was one of the great

points of feedback that we got.

And then we'll be opening that up also for feedback. Is that the right way to do it? Are we not thinking about it appropriately? You know, what's the reason for the change? Are you just doing cost improvements? Is it gaining process efficiencies, error proofing? Are you responding to a complaint? Is it, you know, really resulting of a CAPA?

What exactly is it that we can start parsing this data out a little bit better at in making more informed decisions and start really learning what the model is doing in terms of, you know, shifting the dynamic.

So I think Robin mentioned it. The idea here isn't to say, hey, for you it's a free rein. You can run forward with this. We're actually getting better information that allows us to make better decisions around that which is where we can shift a lot of this burden from.

You know, we want to be able to really focus on the idea that we've got a lot more increased confidence and trust. You're engaged. Just even

willingness to go through the appraisal and show where your standing starts opening that dialogue.

You know, we want to focus on value from the submissions. If we're asking for something it's not just about the review, can we do more with it? And then if we really think about what we can do there's a lot that we might be able to really move on the way things are done right now.

And that's fundamental to I think what we want to assess to the pilot because we want to in- -- as we move forward if this starts to operationalize we can expand. And that goes into other review activities and other ways we look at things so it's the start. You have to start taking a step somewhere and I think this is where it was very easy to start making some changes.

Again, moving away from just generating documents and artifacts for the sake of the regulator to what are value added evidences of data that we can actually work together on.

New understandings of performance and what that means where our manufacturers are. And then on

both sides we want to increase the capacity for improvement. We want to drive improvements into this pilot. We want to drive improvements into the program. We want to drive improvements within the manufacturing industry.

We need capacity to do that. I don't know -- I'm assuming you guys are in the same boat we are, but, you know, our reviewers are working day and night running through submissions. Is there a better way to do that so that they can then focus on elements or developing new strategies to really address that patient value piece?

I already got the pilot governance. Robin went through that, and that, and that. I think some of the slides got merged. Huh.

Well, if that's the case I'm just going to go straight to questions because I'm not sure what happened to the last couple of slides. Are there any questions, any concerns?

MALE SPEAKER: I have one question. This morning we heard Captain Boyd explain that you could scope for the particular site, but when I heard your

presentation I have a question regarding reduction of burden.

Should there be completely compliance between the list of devices and the establishment registration that we have with FDA when you compare to the scope mentioned by Captain Boyd. What I'm concerned about is if we choose one product, one site --

MR. VINCENTY: Yeah.

MALE SPEAKER: -- and the device listing and registration is different what is the FDA approach?

MR. VINCENTY: That is -- that's a great point and we didn't bring that up explicitly because that is part of what FDA does as part of their verification.

When scope products are selected it's part of the enrollment form we do check and make sure that, you know, the registration listings at least match and, if not, then it's a discussion.

Right now we're trying to figure out what was -- why is it not matching and that would be the first engagement piece if that were a situation where

it happened. It hasn't happened in the ones that we've enrolled up until now, but it's a very fair point. And we do do that as part of the verification within that five-day time frame that we're looking at.

MALE SPEAKER: So if there's no complete match will examples such as product being taken out of the market that would be -- because it will no longer be manufactured. Not to remove it from the marketplace, but --

MR. VINCENTY: But is that -- in the situation where that's the intent to remove it from the market?

MALE SPEAKER: Yes.

MR. VINCENTY: So that's -- I think we've already got some ways to engage around that piece and when that happens. Again, that'll be part of the discussions to occur. And we'll get a better understanding as to what the intent is, you know, is it even being distributed here in the U.S. at that point in time or what's happening.

But if that situation arises, you know, we will deal with it individually.

MALE SPEAKER: Hi. My name is Fias Man (phonetic) and I'm from (indiscernible) and I'm from Mutual Diagnostic industry. I believe in looking at this thing right now, looking at PMA (indiscernible) that's a big benefit for PMA processes. But I think this process some really now interested in the CMMI model.

But my question is what is the expertise level you have within the CMMI Institute? Because Mutual Diagnostic is very -- you know, special expertise is needed to look at those processes and systems as well, too, different from medical devices only.

So what are the level of qualifications you have in that IBD industry aside?

MR. ZACK: So just I had a little trouble hearing you so I'm going to repeat the question because I think you're asking specifically within medical devices there are -- there's niches even within medical devices, right?

There's general medical device knowledge and then there's IBDs, combination products, so on so

forth, right? You're asking how do you assure that your appraisal team has the prerequisite knowledge of your particular industry?

MALE SPEAKER: IBE area.

MR. ZACK: Right.

MALE SPEAKER: That's correct, yes.

MR. ZACK: So our working groups have actually been working on this particular question and saying what is an appropriate amount of medical device experience. We've definitely determined that an appraisal team has to have an appropriate amount of medical device experience.

There's been a lot of question as to what is appropriate. There's a clear path to become a CMMI lead appraiser that Kim discussed earlier and we've been going back and forth as to is that somebody has to have a RAC, right, an R-A-C, credential. Does that mean that they have to have 15 years in the industry?

But ultimately it's we are assuring that on any particular appraisal team in working with the organization that that appraisal team will have a lead appraiser and will have somebody that also has the

requisite knowledge to execute the appraiser with high fidelity.

So if in your space you're talking about IBDs?

MALE SPEAKER: Yes.

MR. ZACK: We're not just going to bring somebody along that has just pharma experience, right. It would be let's make sure that we're lining up an appraisal team so that the language and the processes and the operations that you execute make sense on that particular appraisal team.

MALE SPEAKER: And so far your experience has been in the area you have people looking at that or --

MR. ZACK: We haven't had to do an appraisal yet so we have -- no, we haven't done that yet to be honest. But I have confidence that we'll be able to get folks with that type of medical device experience.

MALE SPEAKER: Okay. Thanks.

MR. VINCENTY: Sounds good.

MR. FRIEDRICH: Hi. Joe Friedrich, Boston Scientific. Cisco, appreciate this -- your leadership

in driving the culture, if you will, forward on this. I think this will be a great benefit to both industry and ultimately to patients.

Can you talk a little bit about the mechanics around that changing from the 30 day manufacturing changes to what looked like maybe like a 24 hour?

Was that -- is that considered a prior approval still in practice, it's just a shorter time frame and then the mechanics around what you actually put into it is dramatically altered?

Could you kind of speak a little more on that?

MR. VINCENTY: That's exactly what we're looking at right now. It's still considered a prior approval. Again, we're not changing regs with this activity right now. We're learning and identifying if something needs to change, how do we change that, and what's the best way to do that.

So it is really just a significantly reduced timeline and then, again, the details that are submitted in there, right. We want this to be as

efficient and easy to generate as possible so that not only from your side, but, you know, we can incorporate that into maybe some of our internal data systems ourselves a little faster and then do a little bit more of that kind of cross looking analytics around that that we really can't do right now.

But it really will be just very basic information and then those data elements for each of the changes going through.

MR. FRIEDRICH: Great. And then just a quick follow up. So we're participating in the pilot. We received a letter for our acceptance into it which is great so we're very excited about that.

Will there be something similar like a letter issued after the appraisals completed and the data is provided, summaries are provided?

MR. VINCENTY: Yeah. So we're looking to make sure that something along those lines is received once the appraisals completed and we've accepted the information here at FDA so you'll have that information for yourself. And then that's also going to be your reference point.

MR. FRIEDRICH: And then that becomes kind of the mechanism for us to sort of --

MR. VINCENTY: Yeah.

MR. FRIEDRICH: -- adopt the new process?

MR. VINCENTY: Yes.

MR. FRIEDRICH: Awesome. Thank you.

MALE SPEAKER: So, Cisco, we definitely appreciate the thoughtfulness in terms of laying out the benefits that you described. I think they're a great synergy with what adds value for us.

When do you see the details being available so that we can start realizing some of those benefits for sites that are pilot sites?

MR. VINCENTY: In which sense I guess? Because there's the details of, you know, the individual components and mechanics that we've got right now we can start making some of that available even as we make these slides available after the fact at least for comment and for additional elements.

For the ones who are enrolled now and participating we're going to try to implement that as part of, you know, the early learning also so to

figure out what needs to be debugged in our process. So that'll be available, you know, for the early enrollees and participants.

MALE SPEAKER: Okay. So the simplified submissions and then starting to plan around our, you know, if we have some PMA applications coming up we can start thinking through and working with you on --

MR. VINCENTY: Yeah.

MALE SPEAKER: -- how that simplified structure works and start planning around that?

MR. VINCENTY: Yeah.

MALE SPEAKER: Okay.

MALE SPEAKER: Thanks, Cisco, for the update. The facility and submission side is very clear and I think, you know, attractive for PMA devices. The facility side I think is equally clear for 510K devices.

But can you speculate or comment on, you know, where the submission support or let's say incentives might come for 510K devices both therapeutic and IVD?

And also what's, you know, the best way for

potentially interested stakeholders to engage you in the conversation?

MR. VINCENTY: So we've actually -- we've heard that feedback quite a bit and we've actually started internally a team to work on really looking at the 510K submission activities from that same standpoint.

They've started making some pretty good progress, but that also leads into the reason why we're collecting those checkpoint metrics. Because that's also another piece of how do we make the transition from, you know -- in manufacturing submissions it's very easy, it's very controlled for us to make some of these changes. We've got tangible elements to work off of.

When we're talking about the 510K space the elements and issues that we've got to consider are more on the design side. So we're looking to figure out and identify what are the right different set of metrics, what's the right different set of approaches, what expansions may need to happen even in terms of the CMMI appraisal process elements that get included

in order to give us that confidence.

And then here are the kind of shifts that we're looking to with that piece because I think on the 510K space -- and it's great that you mentioned it because I think the group that's leading that sub team is actually from our IBD group and they've really been thinking through that activity on their end, right.

How do they really accelerate that and what are the changes that we would like to see to maybe see that sustained data? And that may be completely different than what we're looking at right now. It might be some other submission type of element that goes on that we look at over time or not to, you know, use a term lightly, but more of a, you know, post-market evidence generation activity.

MS. NEWMAN: So I'm just going to add for clarification most the interface you do for Case for Quality is with the Office of Compliance and I understand that. But please understand that behind the scenes the Office of Compliance is working with OIR and ODE. We're all working together to try to figure out the best path forward because this is not

just a compliance activity. This is quality.

So we're working with the other offices. The PMA thing I think we've got that pretty much. We understand that. The 510K is a work in progress. But we have some time and we're going to get that worked out.

MR. VINCENTY: As for the best way to engage, there's feedback, there's emails. If we've got -- any time we're going to start moving in that direction we do try to engage a lot of the experts and stakeholders, bring them to the table, get their thoughts here's what we're looking at.

So there'll be more opportunities around that once it starts evolving. And then if you've got any thoughts there's email addresses, you could always contact me, we could set up time. That's the way we've really been learning and engaging on this end.

It's something we could probably bring up through MDIC and maybe take on as a topic there.

FEMALE SPEAKER: Thank you for the presentation. I found it very informative. One question more maybe on logistics regarding the data

elements you mentioned.

It wasn't clear to me if this will be something that the manufacturer will enter data into a database maybe somewhere to the likes of FURLS or will this -- will be still be submitting these data elements through how we do today for 30-day notices?

MR. VINCENTY: Yeah. I'd love to be able to say we're going -- and maybe that's a goal down the road we have an electronic submission format similar to FURLS. It'll be very similar to what we've got right now throughout the pilot just because that's the mechanism we've got and it's easy to at least work within that and then see what we can adjust and which ones are the ones.

Because we may actually find out that the other data elements we defined aren't the right ones and we need to adjust that. If we put that into our system like FURLS that would take another three to four months to readjust afterwards.

FEMALE SPEAKER: Thank you.

MR. VINCENTY: No other questions? Excellent. Thank you.

MR. BOYD: All right. Next so we're going to hear from a couple of manufacturers regarding the value proposition and their perspective.

First we have Nathan Tenzer from Edwards Lifesciences. And Nathan is the engineering operations and project management leader at Edwards. Come on up.

MR. TENZER: Thank you, Captain Boyd. Thank you, Cisco. We really appreciated the partnership on the program up to this point.

Edwards is extremely excited about this initiative. You know, it's really easy to get amped up about affecting patients and that's what -- that's what all of us here do. All of our companies we're really motivated by the end patient and this is going to impact the ability to get technology out into the field and incentivize the investments that we make to ensure these products are high quality.

So we were asked to monetize the incentives that were proposed. And so we came up with a couple. I'm just going to go through three slides here and you guys can check my math and throw things at me if I'm

off here.

So we have -- our typical audit is about ten days and a minimum number of people in the back room, ten people to make some of this math pretty easy. So we look about $140,000 per audit. This is what a typical, routine surveillance audit would be.

The problem with our world is we don't get too many of the routine audits. We get the -- we have a new product that comes out about every 18 months, 24 months on a longer cycle. So the PMA QSIP audits are coming very, very frequently.

So there's a major advantage with sites that have enrolled in a pilot program here where we would realize this benefit pretty immediately. If you do the math and you have a complex site it's $35,000 for the assessment. That means if you had one audit in four years that this has paid -- this program has essentially paid for itself.

So, you know, we look at this this is great, this is very nice. The primary breakdown is in the salary. This doesn't reflect any of the savings that we would get or any of the projects or delays that we

have to projects by rerouting any of the folks off of what their normal day job is.

So this is great, but this isn't the one we're really excited about. Here's where we get really excited. So we looked at one of our flagship PMA products that came out. Am I too far? Okay. I've never been accused of being quiet before, but okay.

So one of our flagship products at PMA product we took the entire lifecycle and we analyzed this over three years. We have about 70 PMA 30-day submissions. So this is 80 hours of work for on average for each one of these submissions so you're looking at just about a half million dollars just to support this.

So this is the part we get really excited about when Cisco says we can turn this around in 24 hours on these types of submissions as opposed to 30 days we can change the distribution here of what we're really submitting for because most of these are fairly statutory, they're required.

We have vendor processes here, capacity, we have processor specification updates, and then you've

got that small sliver there of 17 percent for cost savings. And we're kind of bottlenecked on how many submissions we can really submit to drive some of these big improvements because of some of these other activities that we really have to submit.

So this is very, very exciting for us. And, you know, if we did our math in 2016 just for the facility that I -- that Rob and I are from that's $127,000 just in submission there so. That doesn't even include the impact of any delays for cost improvements or those types of enhancements. So that's the second piece.

The third piece that I think is worth going through here is the unintended consequences. Now this is one that was pretty eye opening for a number of folks in the agency when we went through this. And this is an example of a RO/DI water loop, a reverse osmosis deionized water for those of you who don't use that.

Now as you look at the requirements this requires a PMA submission and you think 30 days, okay, not that big a deal. But there's really a lot more to

that submission. It's two weeks to install it, it's four weeks to test -- test the water system, then you have to prepare your 30 day, then you have to wait for your 30 day and you have to anticipate some level of this not going perfectly according to plan.

So you're looking at 12 weeks to really prepare this and get this approved. In the meantime anything that's produced in this clean room is on hold while you're waiting for this process.

Now in a PMA product world you typically don't have 12 weeks of inventory on hand or you don't have the ability to build up 12 weeks of inventory. So you end up taking an alternate path which means you build you big building and you had your warm water loop and you were all set, but instead of spending $1,300 to add that last drop you have to add $65,000, $66,000 to add a whole nother water system in because you just don't want to touch anything in your space.

So this wasn't the intent of something like a 30 day. It was meant to keep the agency informed. But it's real world impact that's hitting our facilities and driving some of these costs frankly

completely unnecessarily.

So we see this -- we see this partnership completely as a win-win. And that's the information I wanted to cover so thank you very much.

MR. BOYD: All right. So next we have Frank Meledandri from Zoll. Frank is the manager of the quality assurance group with Zoll. Frank?

MR. MELEDANDRI: All right. Thank you, Captain Boyd. So what I'm up here to do is talk to you guys a little bit about some of the benefits that we've seen through working with Cisco and some of the changes that the FDA has been requesting and suggesting to us.

So a little background on me. I'm a quality manager of Zoll LifeVest. We're basically a wearable defibrillator. It's a treatment option for sudden cardiac arrest. It offers patients advance protection in monitoring as well as improved quality of life. So it gives them a piece of mind should they have a cardiac event the device will treat and, you know, bring them back.

We're a Class 3 medical device so we're very

heavily regulated, but we're also a growing company at this time so we are very heavily paper based. And what we're trying to do now is get into, you know, commercial off the shelf software such as Camstar for MES and ERP integration.

So, again, rapid innovation, increased variability in manufacturing, you know, regulatory challenges, increase cost, time of implementation. We needed to improve speed, visibility, control.

And implementing this technology enables operational manufacturing quality excellence. So, again, we get this technology and we're all excited, we're all ready to use it. And, as you know, you have to validate the non-product software and that's where the challenges and the cultures started to shift.

So go live, we have this new software. We're all excited to use it and then the change request came. The CSV. So if you know of computer system validation you may have some of the issues that we did. And what we were doing is taking the approach, the conservative approach for a very heavily scripted, conservative approach because of being

afraid of the FDA coming in and how we were going to be audited.

So talking with Cisco and those guys, you know, they gave us the ideas and the thoughts of, you know, different ways of looking at things. The business impact very long, detailed, air prone, test scripts. Large, large, volumes of paper and a very intensive time, multiple sign off stages.

So, again, we want to utilize this software yet trying to make changes to it was going on and on and it was delaying things. The CSV team was always blamed for extended timelines because validation would take forever. Systems would be modeled in April. They wouldn't even be scheduled to be validated until September because the backlog -- backlog was so large.

So the impact it had on our culture was, you know, a very rapid decline in overall morale surrounding the system and the CSV process. So, again, system was great. You know, we were paperless, yet we couldn't use it.

And a lot of the historical folks, you know, why did we get this system? We can't even utilize it.

You know, accelerated pace of change requests they were outpacing the CSV resources. So, again, more modeling changes than we had the resources to validate.

Training was definitely a barrier. It was a very, you know, paper-based approach that was hard to bring others on. High frustration levels. Nobody wanted to touch CSV.

And finally once we started to get some ground my engineering team -- the lead engineer, subject matter expert, she actually quit so then I really was left in a bind of, okay, now I'm stuck. How do we even find somebody that can do this?

So I started reaching out, you know, Jason with Camstar saying are there people in Pittsburgh that are even using Camstar somebody I can find somebody to take from -- you know, but we didn't go that route.

So the awakening was we learned that there was an initiative going on led by Cisco, Jason, and, you know, folks at Medtronics, Boston Scientific looking to shift this risk-based approach to computer

system validation. So, again, along the lines of the Case for Quality this was one of the initiatives that they were looking to change, a big paradigm shift.

And one of the slides they had come up with was an approach to, you know, risk-based validation, vendor qualification, how strong are your audits of, you know, say your MES, your Camstars, your (indiscernible) and then utilizing high-scripted testing, medium unscripted testing, and low ad hoc testing.

So, again, based on the level of your change how much validation are you going to perform? You don't need to do the heavily scripted for every change. You don't need to pull out that test document and, you know, mark up 60 pages with N/As just to validate a workflow and a couple past selector changes.

So this slide came from when we were at Medtronics in June and it was a great eye opening for us. So we have the three levels, but how do you, you know, tell the FDA why did you select high, why did you select medium, why did you select low?

So we really looked and we wanted to base things on patient risk, regulatory risk, and ask the questions around the types of changes that we were seeing. You know, we had a backlog of over 90 changes. Each one of them was different. Is it a customization, is it a configuration, is it out of the box?

Again, we were doing everything at the highest level. So once we started getting these questions we started developing algorithms around the types of questions just such as you have a change. Is it a customization, is it a configuration? It'll follow a path. Is there human -- is it collecting data, yes/no? It'll follow another path. Is there human review? Is the system making the decisions? Another path. Has this been validated in the past?

And in the end ultimately replying on that off-the-shelf software vendor qualification example again with Camstar. They're very strong so they're very low risk. So we would take that into consideration at the end and you would see, you know, the yellows, high, mediums, and lows. And that would

take you to what template to use.

So, again, we then take those, we take these flow charts and we follow the path and we actually attach it to the change form. So, again, completing that path if the FDA were to come in and say, well, why did you select this? Now we have an easy risk-based approach to show that.

So, again, we then created templates. We didn't -- we don't use protocols. These templates can be scaled should it be a large scripted validation for say a customization to use it over and over again. But for the most part we create these one offs and we -- you know, you can scale them however you need them to be. We attach them to the CSVs, you know, and we'll move on.

So, again, around the culture change, the culture shift is what I wanted to really touch on. So the impact that we saw, you know, simple things, process validation times. Going from 38 days down to 7 days. And, again, a lot of that was through paper-based, you know, review times.

Taking advantage of testing that was already

being performed and including that with the validations. So we need to do 22 runs for non-product software validation?

We were choosing to do 22 runs because that's what we did with our product. So, again, knowing that the vendor Camstar was strong we knew if it was a certain path it's going to work 22 times just like it worked the first time. So we could start taking advantage of that and documenting those advantages, as well.

Again, we were at 90 changes literally in the backlog. The culture was very, very bad. People were butting heads. Modeling groups, you guys don't have enough resources. It was not good times when we were going through it.

But now we are at zero changes in the backlog and the advantage we are getting is we are implementing changes real time which is what we want to do. We want to affect the patients. We want to get those changes into the system. We want to build a better product in the end.

So, again, another example of how working

with the FDA through some of these initiatives is allowing our company to do that and meet those goals.

Upgrades to the systems. Just because we're knocking through this backlog we're able to upgrade our system, you know, four months ahead of time, fixing bugs, system improvements, efficiencies gained. And, again, CSV numbers we have a lot of examples of these. But example I have here 18 days to 3 days just for a workflow configuration update.

So what we did with these last two is we actually ran a bunch of computer system validation through our old process and then we did it again using our new process again just to show a before and an after. And initially people weren't happy with that because we didn't have time to do this, but we did take the time so that way we could have the metrics to show the before and the after.

So, again, once we started to make these changes and this is the final slide, the conclusion. People went from saying you're taking too long to do all your validation to this isn't enough, you know. There's no way this is enough validation. There's no

way this could be right.

Yet my boss -- my director and I were on the phone with the Cisco's, with the CSV teams and we heard all this. So we -- we weren't prepared for all the pushback on the historical misperceptions as you drive these changes.

So something just to be aware of, you know. it was a big change to the culture to shift. So don't let these misperceptions hamper creating the value with improving an innovation whether it be with CSV or the Case for Quality. But just be prepared for that.

You know, the engineers they're talking with some of the folks last night. They want to make the changes but yet you take it to the regulatory bodies and they put the brakes up. They're the ones that are, you know, scared to make the changes.

So even getting my director on board was a big help because he let me do what I needed to do to improve the system. But we wouldn't have had that had we not been working directly with the FDA and with Cisco and getting some of the great information that the team was putting out to us.

So, again, finally some of the changes on the culture. We allow us for faster system improvements, getting those changes to the patients faster. Faster training, onboarding. We were able to hire not a subject matter expert, but because we created the process we were able to hire the right person and train them to how we needed them to run the system. So I have another really good team in place now.

Team morale just people getting along. It's so much more of a better dynamic right now. And just to ensure the consistent process is focused on doing what's best for the patient and what's for the business, you know.

As Cisco says, we don't want to create processes that, you know, hold back from the innovation and the -- you know, from taking an off-the-product software and utilizing it to implement changes faster.

And doing some of these things with our ERP and MES system such as Camstar we were able to do that. So that's pretty much my discussion point was,

again, just around the culture some of the changes that we did we had an enormous need for this because of the way we were doing computer system validations.

Talking with others I see that there are examples out there where people are going through this so if you have any questions later you can definitely ask. Just as they're learning for Case for Quality, we're learning on this, as well.

We were growing -- it was about a three-month process to take it from, you know, just this conception back in June when we were Medtronics at the event to running it through the last three months and doing some befores and some afters and getting everybody trained up. So it was -- it's been a great three months. People are a lot happier now so that's all I got. Any questions?

MR. BOYD: We do have some additional time for questions if people are interested in asking either Frank or Nathan questions regarding their presentations or we can let them off the hook.

All right.

MR. MELEDANDRI: I thought he was coming to

ask me a question.

MR. BOYD: Here's one. Here's one.

MALE SPEAKER: Actually I just want to say thanks to Nathan. We see basically your -- the pains you went through, you know, weekly with a lot of the people that we work through. And I'm happy to hear that folks like Cisco are reaching out to help everybody understand what the processes are and how to best, you know, satisfy what people are looking for at the FDA.

MR. TENZER: Thank you.

MS. NEWMAN: So I want to make one follow-up comment to this just so you understand that what we're doing here at the agency this is the tip of the iceberg. Because what we're really doing we're looking at every process that we engage in whether it's this or recalls or how we handle all of our interactions with wording letters, everything and we're asking how does the patient benefit from that.

And if the patient -- if there's no evidence that a patient's benefitting from the actions that we're doing that means that that action is not adding

value to the process. And so we're looking at everything.

So if you have a question, if you have a concern you want to talk it over, brainstorm with someone from the office I highly recommend that you do that because that's really kind of key in understanding what is the most efficient use of our resources.

MALE SPEAKER: Can I not let those guys off the hook real quick?

MR. BOYD: Go right ahead, sir.

MALE SPEAKER: Yeah. So this might be more in the direction of Nathan, but I appreciate the perspective on the culture side because I think that's massive and perhaps the costs of having a culture that feels stymied to drive continuous improvement. It's hard to measure.

But in that regard, did you guys try to quantify how many changes, improvements were not implemented due to the real and perceived obstacle of making regulatory prior approval submissions?

MR. TENZER: We did. It was -- it's a --

that was a very active discussion. We -- but because we chose to look at a product that had run through its entire lifecycle we didn't have great data on what was -- what was truly brought to the table versus what was kind of an idea stage. And it was really hard to get numbers.

And I think this -- we're not alone in our organization on this. I think it's really hard to get the number of times somebody says, oh, I bet we could -- oh, no. That's going to take a 30 day.

You know, so --

MALE SPEAKER: Bingo.

MR. TENZER: -- that happens all the time so getting really accurate data on that and the potential savings is quite complicated.

MALE SPEAKER: And I think those very difficult to quantify costs overwhelm the ones that we can quantify.

MR. TENZER: I agree.

MR. BOYD: No other questions or comments? All right. Well, with that thank you for your attention this morning. We're going to break for

lunch until 1 o'clock. So if you've got your lunch ordered it's right out there. We'll reconvene here at 1. Thanks, everybody.

(A brief recess was taken.)

MR. VINCENTY: So as we get started I just wanted to take a moment and thank Nathan and Frank earlier for their presentations, their perspective on things.

A little bit of context. You know, we've got this Case for Quality initiative going, but there's lots of other moving pieces that are -- that are a part of what we're doing. We're very aligned.

And for some of you who may be really paying attention with what Digital Health is trying to do and that touches a lot on the software space and, you know, Frank was able to come in and kind of share his experience in terms of some work that we're trying to do that bridges kind of a gap in between.

But it was a great story on really what is the benefit of that rapid implementation, right. What is it -- the value that that brings and what is the change that that actually can drive even within the

culture of a company.

And I think Nathan's not here yet, but he had actually brought that up in some earlier engagements, too. It's just that shift that happens when you can actually implement some of the ideas and the improvements that you see.

So it was a great demonstration of something practical, tangible that, you know, somebody actually took some initiative and took some courage on and try before we even got a lot of this off the ground. So I just wanted to make sure that they got some credit for the effort they've done.

Coming up next and what I'd like to do is really introduce you to Cyndy Grossman. She is with Faster Cures. And she's going to really give something that we really started this whole discussion off with a lot of that patient perspective.

We heard some great points earlier how do we start making some of this transparent to the patients, right? How do we know what they care about? Cyndy's done a great job of bringing up that point.

I don't think there's an easy solution, but

I'd like her to come up and really give that perspective because that's something that I think we should all be challenged to try to figure out how do we make this possible moving forward.

So with that, Cyndy?

MS. GROSSMAN: So good afternoon, everybody. And I appreciate the opportunity to come here and speak to you all as well as the folks listening on the webcast. I'm Cyndy Grossman. I'm associate director for science of patient input at Faster Cures.

For those of you who are less familiar with Faster Cures, we're a think tank/action tank here in D.C. and we're a center of the Milken Institute. And really our reason for being is to accelerate the biomedical research enterprise and to get cures and treatments to patients faster.

And we really believe -- we've been around for about 15 years and we really believe that one major catalyst to accelerating biomedical research is the patient voice and patient engagement. And so we have a robust program called Patient's Count where we really tried to help the system think about ways to

engage patients.

And my role was created about a couple years ago to really build out some of the scientific underpinnings to use patient perspectives to gather that data and use it in our decision making as an ecosystem.

And so basically what I want to do and I just really want to applaud FDA for the efforts that they've taken to really elevate the patient perspective in their decision making and to elevate it for the ecosystem.

And I want to applaud this group in particular for thinking about I know you all are really heavy in the technical aspects of quality and you're deep in it. And what my job is is really to kind of take a step back, kind of bring us a little outside of your areas and your expertise in manufacturing and product development and really try to think about what it looks like -- what the system looks for the for pat- -- from the patient's perspective.

Now we're not a patient organization. We

work closely with patient organizations and we conduct some survey research with patient organization through a PCORI Patient Centered Outcomes Research Institute Award.

And so what we did was we surveyed about 700 patients and caregivers across the system. And the other area that we work closely in is patient reported outcomes. And for that we're really product agnostic. We're really looking at both drugs and devices and both -- and combination products and how those are working for patients and what outcomes matter to patients. And so those are the two areas I'll touch on today and then I'll also have some time in the panel to talk and answer questions.

But I want to frame my remarks as two -- in two ways. One, kind of what's not -- what's changed in patient engagement, what's different, and kind of what's not different.

So in the what's different framework, well, patient engagement as people actually younger than me say it's a thing and so it's happening. And really what we're seeing is it's less of pushing the ball up

the hill in terms of understanding that patient engagement's important and it's a value to the system.

And now the conversation has really shifted to how do we do it? What does that look like? What do you mean by patient engagement? How do companies and organizations partner together to make sure that there's meaningful patient engagement? And what's the value add for the patients? What are patients looking for when we talk about patient engagement? Are we kind of overburdening them or what kind of level of engagement really do patients want?

These are complex issues and I don't have good answers for you or easy answers for you. But I think that the conversation has really shifted from is it important to engage patients to sort of how do we do that. And the fact that -- and trying to think from the patient's perspective and collectively together, collaboratively how to do that in a meaningful way.

And the other thing that has really shifted in the landscape is wearable devices. Now I don't actually have one. I don't know how many of you do

sort of have sort of trackers or i-watches or whatever those things are. I'm a leadite. But that landscape has really shifted things in terms of what people expect related to their healthcare.

And I emphasize that because it keeps coming up for me as I think about patient health data, patient's engagement with data in the health space and how to collect their perspectives in a meaningful way.

And recently I just read a pamphlet from Stan -- Stanford Medicine and they highlighted some really kind of interesting data that reflects what we saw when we interviewed those or we surveyed those 700 -- over 700 patients and caregivers.

So I'll just throw a few interesting things out. One was 84 percent of patients feel comfortable with vital statistics like blood pressure and basic lab tests being shared within the system and across the system.

And I don't think this actually exists, but correct me if I'm wrong. There are also 70 percent of patients reported health information collected from a smart toilet is actually reasonable information to

share across the system.

And then but only 74 percent -- I know, right? I don't -- I don't actually know if that -- we were having an internal discussion in our office actually whether that exists.

But the point is that only 74 (sic) percent are comfortable with their health record being shared. And yet we know how powerful just information collected at the point of care and in the context of ongoing health especially for people living with chronic conditions is to the system, is to provider decision making, is to shared decision making, and is to the product lifecycle in terms of understanding patient unmet needs. And only 44 -- 47 percent are comfortable sharing that information.

Now our survey found -- and this is what I'm going to get at in terms of what's not different. Our survey found that what's not different is I think this 47 percent. Our survey found a little higher, about 60 percent of people were comfortable with sharing their health record.

But if you overlaid that with trust in terms

of who has access and who the information is shared with and who holds that information and is able to share it around the system patients trust, as you might suspect, providers and healthcare systems the most and they trust companies -- insurance companies, pharmaceutical companies, and device manufacturers -- the least.

So there is a trust challenge that I think probably most people in this room and most people on the webcast aren't that surprised by. But it really reflects that we have this high desire to engage patients and this low level of trust amongst the community.

And I should say that the 700 patients and caregivers that we surveyed were pretty engaged. I think we're still really at the tip of the iceberg in terms of the patients and caregivers that we're talking to and so these are engaged folks and they're not trusting of the system.

So what -- why might that be? And we basically have hypothesis at this point. It's important to dig into this a bit more and we hope to

do that over time.

But we think that part of that has to do with a transparency issue. When we asked patients whether or not they could tell where their data was shared in the system and who used it and what it was used for in decision making the majority of patients said they had no idea. And they had no idea how to find out that information.

And so how can you have higher levels of trust or increased trust without some change in the metric of transparency?

And so as we think about what patients want in the system which is one of the reasons why I'm here before you today I think it's important to think about what they would use this information for. So it's not just that the information is floating. We need high quality information, they want high quality information, you all want high quality information, right?

They want to use it for decision making and to better their care and to make care -- better care decisions. And importantly from a patient

organization and group standpoint those groups want to drive product development to match unmet need. And if you don't know what the unmet need is you can't drive product development toward it.

And so I actually want to keep my remarks relatively brief because I think there's a lot to dig into and I'm much more interested in the questions that you have for me than I am hearing myself talk.

But I'll just close by saying that I think that this Case for Quality and this effort to try to understand product quality -- and I understand and I've heard Dr. Shuren talk about sort of the Good Housekeeping -- and Robin talk about the Good Housekeeping Seal of Approval and I think that that goes a long way.

If you think about what patients have access to now, I can understand how my healthcare system is doing in terms of which hospital might have a little bit better outcomes on a particular procedure. And there are a lot of people -- we're having our annual meeting out in San Francisco and there are a lot of folks that invested in trying to help create greater

transparency in the system. And so I kind of feel like that's going to happen to us so we probably all want to kind of collectively figure out what that should look like together.

And so I think there's a lot to be said about this idea of having some sort of process where all the hard work that you all are going to do to make sure that you're meeting the quality standards and embarking on some novel ways to do that is -- somehow has aligned to being able to be communicated and understood to the public. And if you don't engage the public in that effort you're risking missing a bit of a boat.

So I'll just leave it there and I just want to thank you all for the efforts that you're doing to make sure that you are developing high quality and products that meet patients' needs. And we're happy to partner with all of you to do that. Thanks.

MR VINCENTY: All right. So next up somebody's who been actually a very big part of the effort since its inception. I'd like to introduce

Luann Pendy from Medtronics. She's a senior VP of global quality. And I think, you know, she's going to give a lot of the, you know, perspective she's had since its inception and where it's going now and what the potential for this is.

MR. PENDY: Thank you. Thank you. Thank you. First of all, I just want to start out I'm sure that everyone in this room feels that it is an honor to serve patients every day. Not matter what you do it's an honor. You have that honor to serve the patients. But along with that honor we all feel a huge responsibility to have the highest possible quality and reliability in our products.

It became clear to me this responsibility in a recent experience that I had. My 80-year-old mother-in-law needed to get a Pacemaker. Now Medtronic, you know, we make Pacemakers. That's where we started.

This -- the hospital where she was is all about patient choice. It's the choice of the patient. And so she called me, "Please come and help me. They're asking me what do I want."

And I was just astounded by the lack of transparency, the lack of information around this thing which ought to be an automatic thing for me coming from Medtronic for a Pacemaker. What hospital did you go to, which physician do you use, should it be MRI compatible, should it not be, does it matter, with my 80-year-old mother-in-law need to have an MRI at some point in her future? What's the care? Should she have -- should she have a Wi-Fi compatible?

All these questions were coming to her to ask her because her hospital is so concerned about the patient's choice. What I learned as well is that when a person becomes a patient they are at their most vulnerable state ever. And so things like trust and transparency are so much more important at that point in time in a patient's life.

And so just I came away from this whole experience thinking we can do better, we must do better as a device industry to promote trust, to promote transparency. And I fully believe that Case for Quality is one of the keys to success for the future.

As Cisco said, I have been involved since the very beginning of Case for Quality. I'm proud to say that at this point in time because we are ready to roll out some of the most important programs. It was a long time ago I had just moved to Medtronic. I had a new CEO. Jeff Shuren was brand new in his job. Steve Silverman was brand new in his job. And I said I need to bring my CEO to FDA so that they can meet him.

So we made a very elaborate PowerPoint presentation as you know we in the industry are very good at that. We had the elaborate PowerPoint presentation. We were -- I was halfway through the presentation telling him all the wonderful things that Medtronic is about and Jeff Shuren interrupted me and looked straight at the CEO and said, "Can you tell me is there a business Case for Quality? Is quality good for business?"

And I thought, huh, it's my new CEO. Do I need to kick him? Do I need to pinch him? What is -- how is he going to answer that question? And I was very proud to hear him say, "Absolutely. Quality is

most important for business and let me tell you the reasons why," and he proceeded to say that.

Jeff then turned it back to us and said, "Well, you, Medtronic, help me establish a business Case for Quality?"

And so many years ago that was the inception of the work to start to come together. Eventually what happened Stephanie presented it a little bit later. We didn't get a lot of legs on the program until Jeff Shuren, Bill Hawkins, and a number of other people established MDIC.

Because with a public/private partnership that that created it allowed us to have discussions, fruitful, productive discussions between industry, FDA, and all the other stakeholders about what matters, what's important, how we might change. And so since that relationship with MDIC we've really moved forward fast.

There's a lot of current work. I see a lot of new companies here that haven't been involved in all these discussions so I just want to give a shout out to the resources that are available to you under

the banner of Case for Quality.

First of all, within AdvaMed there's a library of successful prac- -- successful practices. Subject matter experts from across the industry have come together to create successful practices. It's -- they're library books that you can take out and learn how might I better do supplier quality, how might I do better design controls, how do the experts in the industry do these types of things. That's available to you to grab.

We're working on creating quality performance metrics. What matters? What matters to device quality, what matters to the patient? These are things that we can all pay attention to.

We talked already about the analytics, the consumers' reports of medical devices another great program. We're also working on culture. We've said a number of times today culture matters. And so the more that we can learn about how to improve the culture of quality within our organization I believe that's the thing that's going to accelerate the quality and safety initiatives that we have.

And then finally the maturity model which is one of the things that I'm most proud of coming out of Case for Quality because that will transform the industry. It will transform how we look at our products and how we keep our products in the highest possible quality and reliability.

So I encourage you all to join the program because it's just going to be important for you to be a part of the process. You have an opportunity to be a part of the pilot. What that means is you have a ticket to influence how this thing rolls out so please, please join.

Now there is a ton of stuff going on. Someone already mentioned we have so many competing priorities. We have MDSAP, we have EUMDR, we've got just the stuff we do every day. Many of us are working bringing Puerto Rico back up. I know there's a lot going on in medical device industry right now, but I encourage you to think strongly about how you might get your organization to put at least one site, one product up into the maturity model pilot program.

So what's in it for me? Why is it that

Medtronic is all in? Why do we feel that this is the right thing to do?

You've already heard from Edwards and Zoll about why these things matter, how these things can make a huge difference in what we do. But let me put a few more points on the table from a Medtronic perspective.

I think it's important because it allows me to focus the resources that I have within the company. Now company has endless resources. There's always a limit in what you have. And so when I can focus my resources on the most important things I can do the best things for our patient. Robin already talked about FDA focusing their resources. We need to the same in industry.

At Medtronic we have about 300 audits per year. These are audits from major regulators that come to our facilities, 300 per year. We have about 66 FDA and MDSAP inspections so that's a lot of inspections. We have about 100 facilities and so that's a lot.

If I use the numbers that were put up there

form Edwards 14,000 per inspection, it comes down to $10 million a year that we spend on these types of things. I don't want to be known as the audit company. I want to be known as a healthcare solution provider. And we do spend a lot of time and money on audits.

Another reason why I think that this program is extremely important is because it will help us make our quality system more mature. Think of it this way. What scorecard would you prefer to have? The scorecard that says all the things you do wrong or the scorecard that says the things you do right and the areas where you might get even better.

Now I know you would agree with me it's the one the things that you do right that you might get better. And I believe as you look at the maturity model what you will see is it will show you, it will -- it will tell you how you can move from this level to that level, how you can move from that level to that level.

And as Robin said, it's your decision. It's your decision which area you focus on to move -- to

become more mature because you're making that based on the products that you have. So I do believe that the maturity model, the Case for Quality is going to move us forward. It's going to make everyone better in the industry.

And then finally one of the questions people ask is how do I convince my CEO, my COO, my CFO, how do I convince the C-suite that this is the right thing to do knowing that it does seem to be a costly adventure?

And one of the things that we've started at Medtronic is to measure the cost of poor execution. So what does it cost us when things don't go right? I encourage all of you to start to look at the cost of poor execution because you will be amazed at the amount of money that you spend tracking complaints, just processing complaints, processing NCMRs, processing product hold orders, processing 483s.

And those numbers when you add them up are huge in any company. And so I think that it's more expensive to be -- to have poor quality than it is to have good quality. And the only way you'll know that

is to start to track it and then take those numbers to your CFO.

At Medtronic what we estimate is that good quality, which I put CAPAs under the banner of "good quality" because you're fixing and preventing issues that come up. A CAPA we estimate can cost between 50 to $100,000 per CAPA. A 483, on the other hand, is far more expensive. We estimate that a 483 goes from half a million to $1.5 million.

And so when I start to think about the program, the maturity model it's leading me to do more good things like CAPAs to fix things, continuous improvement activities, and it's leading me away from the things like 483s that are eventually CAPAs, things that we may or may not have thought were most important to be fixed. But I can put an economic model in place where I can say doing this in the long run is going to save me money.

So let's talk about the perks. And Robin talked about those. First of all, being off the inspection plan. If I think about the number of audits that I have per year, this is a no brainer for

me to think about a site to be able to be certified as mature and to not, quite frankly, to have an FDA inspection.

The other piece that is really, really compelling is the 30-day notice allowances that have been put together. We looked at one of our large manufacturing facilities and they estimate that they actually made 34 30-day notices in a fiscal year which, as we've already talked about, that number is definitely an under call because often times we just say it's just not worth it to go through this process.

But when we looked at those 34 and we look at the specific things that happened within that 34, seven specific projects that happened in that 34, the advantage of having immediate implementation of the change resulted in $1.7 million in that month.

So multiply that by 12 and you can see the huge amount of savings that something like this would happen. And so as a company we don't go out to do something unless it's going to save millions of dollars.

And in this case as we look at the 30-day

notice it's just really easy to say we ought to do this. We ought to do this because it saves us money, first of all, but more importantly it allows us to put those changes in place immediately which is what we're about. And by "we" I mean industry and I mean FDA.

So let's get back to the patients because we really are here about the patients. A maturity -- a mature quality system allows us to minimize the likely -- or maximize the likelihood of meeting patient needs and minimize the likelihood of having product quality issues.

We will all get better over time. This program is going to require that more than just a few medical device companies participate. There needs to be a threshold of participants in the process, quite frankly, for all of us to invest in making it a permanent program.

FDA's not going to change basic operating mechanisms for Medtronic and for J&J and for Edwards. FDA's just not going to do that right, Robin? So it has to be -- we have to have general industry interest and participation in the program for FDA to make those

operating mechanism changes.

I believe that when we -- when we are fully in line with the maturity model program it will allow faster innovation in our companies because we can take those savings and funnel them back into our R and D efforts.

And most importantly, I believe that as we do this we will generate the trust and transparency that's missing. And when we have that trust and transparency we can all truly meet our mission of treating the patients. So thank you.

MR. VINCENTY: So I want to find out if there's any questions for either Luann or Cyndy. We probably can carve out a few minutes is anybody's got anything they want to ask or take the opportunity now.

No? All right. We're going to keep rolling, then. So coming up next, you know, you've had so many perspectives going on. You know, Luann mentioned a lot about, you know, potential even greater savings of what's going -- of what the modifications can do and really the value of that rapid turnover.

But right now I'm going to bring up, you know, George Serafin. He's with Grant Thornton. And he's going to introduce our panel who's really focused around a larger discussion around what are the potential benefits and value for the program as a whole.

And then we'll have another panel afterwards that's more focused on some discussions around risk. But this is an opportunity if you guys have questions to target to the larger panel we've got some that, you know, we'd like to make sure that we covered also. But engage, you know, provide feedback, get that perspective, you know, from the standpoint of even just savings and the benefits that Luann mentioned.

Imagine that, you know, we've already got a challenge issue. How do we make this something that's more transparent to the patient? How do we get, you know, what your grandmother, your mother's perspectives were, you know, addressed a little bit more?

We want to be able to allow you to use those resources to maybe tackle those problems. How do we

engage on tackling those problems versus a lot of what we are really doing now on a day-to-day basis?

So with that, George?

MR. SERAFIN: Thank you, Cisco. Can I ask my panel to come up and join us? We have -- Cyndy's going to join us on the panel. There we go. Thank you.

And we have Joe Friedrich as well, Al Crouse coming, Adrian, and also Hudson up here, as well. So very happy to be with all of you here this afternoon.

And really what I wanted to do with this esteemed panel here is really have a conversation around the value and benefits of the voluntary program really from a number of perspectives. I certainly want to hear around the patient perspective, we want to hear from the industry perspective, we want to hear from the FDA perspective.

So I have a couple of questions to ask the panel and then we'll open it up to questions for the audience, as well.

So, Cyndy, I certainly want to start with you. Dr. Shuren started us off right away in his

opening remarks in saying it always starts with the patient. So my first question kind of building on some of your prior remarks is really can you share with us your thoughts around what's important to the patients with respect to medical devices?

And a second part of that is are they concerned or interested around a compliance profile that, you know, that a manufacturer has?

MS. GROSSMAN: So thank you for this opportunity. And I just I actually want to instead of sort of imparting my pearls of wisdom about patients to you all I want us to think kind of collectively.

Think about a loved one, yourself, someone else in your family or friendship network that you would consider a patient, right. And think about -- let's think about profiles of patients. And I don't have data to back this up so this is just collective thinking, but it's kind of taken from what we've heard from a number of patient organizations and listening to this base and participating on panels like these.

So a patient might be -- fall under the category of ignore it, right? I got my device

implanted and I just really want to set it and forget it. I want it to -- I just want to go right back to normal.

And for those folks they may have a different level of engagement with the device, a different level of decision making around the device. Then there are folks the trackers. Like I have a couple in my family that are just like constantly. Like they know exactly how their sleep was for the last six weeks and how caffeine impacts that sleep and whether or not they're good to go and did they exercise or not and for how long and what their heartrate was, right? The trackers.

So those folks are going to have a very different level of decision making and probably participation with their medical device decision making and the process there of.

And there's also the sharers, right? There was that whole -- I'm not so much of a leadite to have missed this. I remember and maybe it's still going on where you would sort of share your information and there was a sort of social network. And there's still

that for like diet and exercise and other areas, right, so there are the sharers.

And so those folks those are going to folks that want to have not just access to their information, they're going to want to be able to have control over that information.

And so that's all to say that I think we fail on almost all of that except maybe the set and forget it profile. So if we're thinking about the way the healthcare system is redesigned to account for patients and we think about how devices are used within that healthcare sphere, we have to start redesigning for the engaged patient.

I sort of talked about how we're at the tip of the iceberg. I think we have to design for the whole iceberg or for that bottom rung and know that people are going to opt out and that that's okay.

But what we've done is we flipped it on its head and we've designed for the disengaged patient so that the engaged person and the person who wants to share it and understand it and use information for decision making has no access to that information and

the system provides them very little. So I think that's an important kind of model for thinking about the device industry.

I think the other piece when you think about having information about devices and their interaction and what patients want to know I think there's a variety of information that patients probably want to know, but certainly the ability to make a decision on that information and having that information available for that decision. And we do a poor job of collecting that information, as well.

And yet we have a variety of choices. The system has done a great job of giving us a whole host of devices as Luann talked about, but we don't necessarily have the data that is important for them to make that kind of decision.

And do patients care about compliance? I don't know. I don't really care about compliance. I assume that FDA's going to do its job to make sure that people are in compliance.

What I want is a product that is going to help me feel better, maybe return to functioning,

maybe have a better quality of life. There's a whole host of things that I might want. But if that stuff is not -- if I don't have trust that that stuff is tied to compliance, then what do I care about compliance?

I care about the quality of something. I care about how it's going to make me feel. I care about its ability to improve or at least return me to my previous lifestyle.

So I think that it's important to not overthink kind of these levels of what happens behind this system, but that patients do expect a certain level of transparency.

So as a system trying to figure out what that -- and participate with patient organizations to help them determine and help you all collectively determine what that level of transparency should look like because I think it will happen regardless. And I think we want to all be players in determining what it should be.

MR. SERAFIN: Cyndy, thank you very much. I appreciate you sharing those thoughts. Robin, let me

turn to you. You, in your opening remarks, started talking about the program and sharing about potential changes in the regulatory landscape and just the relationship that FDA and industry can have kind of putting up your hands in the upright.

Just wanted to give you an opportunity to kind of expand upon your thoughts there.

MS. NEWMAN: So I think you probably heard from my comments that I see this as a real watershed opportunity. Historically that idea that the FDA is somehow the enemy and, you know, the industry is the good guy or if you're on the inside the industry is the bad guy and the FDA is the good guy, that sort of good and bad, black and white way of thinking is really not only historically unfortunate, but it's actually note true. The relationship has never really been like that.

And we are at a point now where we have an opportunity to turn it in a truly collaborate type of relationship and that's where we need to be. Because, as I said earlier, when we make a decision I'm asking myself how does the patient benefit from that, how

does the patient benefit from that action.

And if the answer is they don't, then we need a different action. We need a different decision because it's not necessarily achieving what it is that we think we're achieving.

And that's the problem with compliance. It is important to comply. As Jeff said, I'm not getting rid of the regulations. So -- at least not yet. But that's -- but it is important to be compliant, but that's not going to get us somewhere.

In the Case for Quality we define quality in context of how the patient experiences your product. That's a very different way of defining quality how is the patient experiencing the product because that gets to the point that Cyndy's talking about. That the quality component of that is it reliable, is it usable, all of the "ilities", usability, reliability, durability. Those are the things that patients care about. You know, adaptability in some cases, certainly utility.

So all of those "ilities", if you will, that's where patients live and breathe and that's what

we have to be thinking about when we think about what makes a high quality product.

Now we have a program right now looking at critical to quality. What is it about your product, what are the key aspects in you design and the way it's manufactured or whatever that are truly the critical components to ensuring that you have a high quality program? That's where the emphasis belongs.

So I think all of this is really pointing to the fact that the relationship between what we have and what industry -- and our relationship to industry is really I think again it's at a watershed moment.

And the funny thing is I will tell you from 25 years in industry -- I just told you 20 earlier, but it's really 25. But anyway, 25 years working in industry my experience was always that what companies want and what the agency wants are really not that different.

You need happy, healthy customers. You need happy, healthy patients. We have a public health mission that demands that patients be healthy and we're maximizing public health benefit while

minimizing any exposure to risk.

These are really highly consistent goals and perspectives. So what we're really doing with Case for Quality is we're just sort of putting our money where our mouth is. We're saying this program aligns those two sets or the two perspectives on essentially the same project or the same issue in a way that we can maybe this time do things that really are effective, do things that really do make a difference in the outcomes of patients' lives.

MR. SERAFIN: Thank you, Robin. Invite the rest of the panel to share their thoughts.

MR. FRIEDRICH: I'll dive in. So I think aligning incentives is very well put. To me and at Boston Scientific we have our quality policy as I'm sure everyone does, I improve the quality of patient care in all things Boston Scientific.

So for us that's the center of the bullseye. You can't do other things that benefit the business if you're not doing that first and foremost.

So when we talk about anything that we're working on in our company it's such a common question

to say how does that impact the patient or how does that help the patient or I'm not sure that's in the best interest of the patient can be immediately a trump card essentially to say that's not the path I think we should take.

So I think giving that -- giving that alignment between FDA and industry the opportunity to say let's work together towards having the best possible outcome for the patients.

And I love also how you characterized the experience piece. We just had all quality leadership from Boston Scientific at a summit recently and the whole focus was patient and customer-centered quality. And all of the discussion was around their experience. How do they experience Boston Scientific? How do -- and that's not just the product. It goes beyond that, right. All of their touchpoints, all of the interactions that they can have and how seamless is it.

So I think that -- that is very refreshing to hear and I think it's remarkable to see this shift given, you know, some of the maybe ancient history

that was there where it didn't feel like those incentives were necessarily aligned so.

MR. SERAFIN: Thank you. Others?

MR. GARRETT: So I'm a clinician by background and not necessarily a quality person. But what's interesting I really enjoyed your opening comments this morning because I think our opportunity is to learn from other sectors that have done this. And one of the best examples I think of collaboration with particularly CDC and CMS is hospital compare where the consumer can really go online and actually essentially look at the quality metrics of a particular facility especially for an elective procedure.

A little bit different if you have a motor vehicle accident or something you come in. You can't really check that. But I think there was a big learning curb for about three to five years where people would go on that site and look and things and say, well, I'm not exactly sure what this means.

And so then CDC came behind that with a standardization. And I think that we would probably

need something consistent with that here too to make sure that patients could fairly evaluate what the data was and then also be able to use that with their medical decisions.

I think the other thing too is to look at this from a curriculum for healthcare professionals that are making or helping patients make these decisions because then they could be better informed about the process along with the manufacturing community.

MR. SERAFIN: Thank you. Others or we'll move onto the next question? We're good? All right.

So before we move onto the next question I just did want to give a shout out to our maturity model team members. You know, George, Kim, I thought you guys did a great job up here before really talking through things and starting to really share with everybody the amount of effort in this journey that we've been on.

I've been very fortunate to be part of it from the beginning. When you heard the comments

around doing the research around what maturity models we could be using in Lifesciences I was fortunate enough to be asked by MDIC to lead that research work. And if you're interested in the details of that there's a paper on the MDIC website.

And right from the beginning when we moved into the maturity model there was always a great level of energy and interest and enthusiasm for a lot of core team members and others that have joined us over the last 18 months as we've been developing this.

So what you're hearing about today is really just incredible hard work and commitment from all of these individuals that are basically in all these sub teams as was described before meeting on a weekly basis, doing work nights and weekends, building -- you know, building all these capabilities for us to take forward while they're doing their day jobs on that. So, again, I just want to do a shout out to our maturity model team and give them a round of thanks for that.

Al, you've been with us -- oh.

(Applause.)

MR. GARRETT: Al, you've been on this journey from the beginning, as well, and also had the opportunity to really be one of the pilots as was mentioned earlier. So I really would be interested in your thoughts in terms of sharing your experience during the pilot and then did you get any benefits out of it?

So not just going through the pilot, but even after now the pilots been done for a while what benefits have you seen with you and your organization?

MR. CROUSE: So first off, I'd like to say that I think, you know, the benefit that we got from going through the pre-pilot effort there was that we really approached it significantly differently than how we approach normal inspection criteria.

Typically with an inspection, you know, we do as most medical companies do. You sit down and talk with everybody before the FDA gets in and tell them don't say anything that they're not asking, stop talking when you've answered the question, you know, don't share anything beyond the very, very specific question that they're asking you.

And so it was a challenge to train our people for this new type of approach that, no, we actually wanted to share some of the struggles that we're having and some of the concerns, but by doing that we can open it up to some areas where maybe we can make some improvements and do that.

And we actually allowed FDA to listen into this and I think it was just as shocking for our people as it was for FDA that we were actually open and honest about areas where we could improve our processes.

We did have a number of areas where they found that because we're a small company and we do a lot of paperwork processing we had some areas in our configuration management that could use some improvement. We had some areas in just our -- we do very manual metric gathering because of the paperwork system so there was some areas where we could automate that.

We also had some project management areas where, again, we have very small teams. So, you know, tight oversight of a small team is not as critical as

it is for some bigger companies where you have a team of 100, 120 people.

So, again, we took those inputs that we got out of that and made improvements where it was important to us. And like in our configuration management we've since automated our non-conforming material reports which were always paperwork and we've now automated those.

So we've learned some things from that and taken those things that we find to be critical, which are indicators of places where we may be having problems and been able to move those forward.

So, you know, much more feeling on everybody's part when the assessment was done that we had areas that would actually improve the quality of the product where as a general rule I don't think anybody ever felt like when we were done with an FDA inspection that we had some good insights how to improve our product so.

MR. SERAFIN: That's great, Al. Thank you. And, again, as was mentioned before, I mean, some great speakers have come up a bit earlier talked

about, you know, value and potential ROI.

But I wanted to open it up first to some of the other manufacturers on the panel. You know, from your perspective what do you see the value of this program for your organization?

MR. FUREY: Yeah. So from a manufacturing point of view -- and I'm 25 years working in medical device industry. It's always been my device and always supply chain engineering.

But I found this morning to be really exciting honestly with regard to the perception of the FDA and how we interact with the FDA. And for me it's very groundbreaking because all the experiences Al talked about I've seen in five or six different companies the same every time.

I spend most of my life at the moment working on leadership and culture. And I have no doubt that as this pilot evolves and becomes reality for more and more companies it will have a huge impact on leadership and how we lead and on the culture on the shop floor of manufacturing plants which is where I spent a lot of my time. I have no doubt in my mind

whatsoever it will all be positive towards the patient and towards the company.

And I think one aspect that maybe needs reinforcement is the whole benefit of agility. So registry hurdles I understand them, we go through them, and it does constrain innovation there's no doubt.

But instead of, you know -- and I hear Luann's point about people wanting to join. To me why wouldn't you want to do this when I think about agility and getting new products and new innovations to our customers?

And to me it would be a competitive disadvantage not to be involved in a program like this and that's just from my four hours this morning. I came with very little research. I've learned a lot and to me this is a no brainer.

And I know it's easy to say, you know, (indiscernible) patient at its core. It's easy to say the words, but there's a lot of work now to make that reality. And I really look forward to watching the journey and maybe being part of that over the next

year or two years.

MR. SERAFIN: I appreciate that, Adrian. Joe or Hudson, other comments?

MR. FRIEDRICH: Yeah. I mean, I'd echo much of what Adrian just said. I'm relatively new to Case for Quality. I'm actually -- I was asked here to Connor Dolan who some of you know. He's half a world away in India right now.

But I am, as I mentioned earlier, going to be participating in the pilot. I'm director for our site in St. Paul, Minnesota. And when I first learned about this and, of course, how excited Connor is. And Connor doesn't get excited about too many things, but he was real excited about this.

And I just sensed just that genuine connection to here we have this opportunity to drive what we're culturally trying to drive internally already and have been on a journey for some time to get -- to become the best possible organization that we can be around quality. And not just even reactive quality, but proactive quality looking at continuous improvement, ingraining that into our culture.

And to see that we're on this path to eliminating or reducing anything that stands in the way of getting the best possible outcomes to patients and the best innovations out to the marketplace, you know, that there is this effort towards that is incredibly exciting.

You know, the incentives become very, very tangible very quickly that we've talked about. And I know maybe in the PMA space that's more evident than what, you know, the 510K perhaps, but clearly the movement is in that direction and that nut will get cracked, as well. I'm confident of that.

MR. SERAFIN: I appreciate that. Yeah. So just a couple of comments there to build on what you were saying and then how -- Robin, I'm interested in getting your thoughts from an FDA perspective.

But, you know, I keep hearing, you know -- Luann mentioned these comments as well -- the culture change. And, you know, I characterize it as, you know, doing things right versus doing the right things. It's really getting to shift the focus.

It's giving the opportunity to open the

aperture where you've been shining this bright light on compliance and now going quality beyond compliance and sustained compliance being -- you know, being more of the focus kind of building on some of those thoughts.

And, Robin, you know, we've heard from some of the industry side. You know, how about the value of the program to the FDA?

MS. NEWMAN: You know, I've never worked anywhere in my life where my team is more mission focused than they are here. I mean, I think to a person everyone I work with at FDA is really all about the mission, protect and promote public health.

And what this does for us really is help us put our energy and effort into the things that actually achieve that goal versus, you know, going out and measuring whether or not a company is doing all the things that they need to do in order to be compliant. And, oh, my goodness, I see an upstream, you know, problem in the manufacturing area. We had a temperature excursion.

That's a finding really, I mean, because I

look at that and I think how satisfying. No. So the point is -- the point is that this allows us to create the kind of relationship with industry, this trustworthiness, this reliable transparent relation of high fidelity -- I love that word, by the way, that you used -- because this is exactly what it's about if you want to meet your mission.

And so for us by being able to focus on that and then create this group of companies or this group of people in industry -- or, yeah, companies where we can say we know you've got it. You understand. We're not worried about you. We're not going to have to invest a lot of resources in you because you can handle it.

It allows us, then, to focus on helping the companies that really do need that hand up. Working with the ones more closely that really can benefit from understanding very basic things like compliance and then as they make their journey through the quality process.

So for us it's exciting to feel like the efforts that we're engaged in will be meaningful and

they will help us to drive that mission in a really tangible and direct way.

MR. SERAFIN: Thank you, Robin. One other comment I want to build on, too, that Stephanie Christopher said in her remarks around MDIC. And this also goes back to maybe answering a question that was asked a bit earlier which is around leading practices or best practices.

And I do think that the opportunity of working through the appraisal and the CMMI methodology, but also MDIC teams has broader ecosystem with AdvaMed -- Steve Silverman's here -- ASQ.

And so for a lot of these companies you can find out what best looks like. You don't have to create it on your own. Although I am a consulting, you don't have to hire consultants to go find this information out. You could if you'd like to, but there's a lot of -- there's a lot of faculties, a lot of assets out there.

And the vision -- not that it's here today. Again, this is, you know, we're walking before we're running here. But the vision is to be able to learn

from this program and to be able to then fuel those -- that information into these other areas so that way we could see the best practices.

And companies can look out and say, you know, Al, you were mentioned configuration management. Well, you know, there's some best practices (indiscernible) and AdvaMed talks about configuration management or learning management or other areas, project management.

And so that's where you start seeing I think some of these other benefits and incentives that can -- you know, that can happen with respect to this type of program.

So speaking of incentives -- and, Joe, you touched on it just a little bit. I wanted to go to you. But, you know, what incentives are most important to you in your organization?

MR. FRIEDRICH: I mean, so I think I've covered on a number of the incentives. One -- the one I really want to emphasize, though, is, yes, there's the -- you know, the cost benefits of not having as many inspections, of having, you know, a vastly

reduced regulatory hurdle to get over for changes in the manufacturing space. That's been well explained.

The one that really resonates for me is the culture of continuous improvement. I spend as much of my energy as I can leading my team and trying to influence my organization to adopt, you know, Shingo principles, lean principles, best practices driving continuous improvement and there's nothing more frustrating to me than when I go down and spend time with builders, with engineers, with technicians and they point out things that they like to improve.

And there's this big hurdle standing in the way of them being able to actually make that change. And many times us determining that we just can't fit that change in given what it takes to implement, you know, even 30-day manufacturing notice. It doesn't sound like a lot, but it's substantial.

And there are so -- I said it earlier. There are so many continuous improvements that often just don't get made. And then what's worse is you have individuals who see that and then they're like why do I even bother, why do I even put in a CI card

because it's not going to get implemented.

So to me the most valuable outcome of this, yes, for patients. Absolutely, that's -- that's truly the end customer here. They will be better served by a genuine culture of continuous improvement inside the company and that'll be fostered by aligning incentives like we're talking about.

MR. SERAFIN: Thank you, Joe. Appreciate that. Others? Anybody have other comments?

MR. CROUSE: I would say as a pre-PMA company, you know, the idea that we can take the pre-PMA inspection off the set of hurdles we need to cover before getting a product approved would be a big improvement.

As most of you know that have gone through a new product development there's all the sets of hurdles that you need to cover before you can finally get the product out on the market. And when you've been funded by Venture Capital and you're spending down that money anything that you can do to move that endpoint back in a little bit is an incredibly helpful idea.

So really appreciate FDA working with us on some of those things.

MR. SERAFIN: That's great, Al. So just wrapping up again what you're hearing from everybody is really that this -- this program you've heard it from a number of the speakers before is really intended to be for everyone.

And, again, I can't emphasize enough in all of the meetings that we've had from the very start it really was to have that flexibility that it had to be for small, medium, and large companies, all different sizes, difference devices.

I mean, if you think about how complex the ecosystem is on the med tech side that was really our guiding principles and coming up with a program that could add value, you know, to any size organization with any type of medical device, you know, that they have.

You know, Adrian, I wanted to turn to you. And Cyndy mentioned in some of her opening remarks around trust and transparency with respect to the patients. I wanted to get your thoughts.

MR. FUREY: Yeah. So for me I am -- honestly I do think this morning is groundbreaking as you said, Robin, in terms of visibility to the patients. And the more I think about the program it is, you know, why wouldn't you engage as opposed to wait and see? I really think it's worth making this happen.

I also think there's a lot of positive the grading of the assessments and doing it plant by plant or facility by facility has a huge win within the corporation. And externally you can promote that, as well.

So the more -- I mean, it's really something I need to take back to my own team and look at and say, you know, how can we possibly help here because it's a win-win, it's a win all around for us. I mean, you know, everything else has been said in different ways by different people.

But, I mean, that's how I approach it, George. I mean, we would be all in. I don't see why not, uh-huh.

MR. SERAFIN: Sounds great, Adrian.

Appreciate that. Other thoughts from the panel around gaining the trust and transparency of patients perhaps through this program?

Cyndy?

MS. GROSSMAN: Well, I would just say that, you know, as you were you all talking and I know that there's a sort of different -- and you were saying that there's different companies and different entities and so we're trying to get a broad -- or you're all trying to get a broad swath of participation.

And I guess as you were talking it was reminding me of one of the challenges that exists in sort of some of the patient-reported data sphere which is that we have apples and orange comparisons instead of apples to apples comparisons.

And so I was just thinking, you know, that sort of that is reflective of if you don't have broad participation, then how do you have that apples-to-apples comparison at the end of the day?

And we're hearing from our patient organizations that that's so important. It's

important in their participation with companies to be able to bring data that is meaningful and that is -- that is that apples-to-apples comparison. And it's important to them in terms of helping their patient population at the point of care.

So any -- and I almost trip over the word standardization and those kinds of things because they're just heavy words, but I think you get the point.

MR. SERAFIN: Thank you.

MR. CROUSE: I'd just like to comment as well that I think, you know, one of the things we'd like to see come out of this pilot is some indications that we could use that would be beneficial information that could go back to the patients.

But I think we're -- most of us in industry and probably at FDA, as well, are struggling a little bit with what that looks like right now. But hopefully we can get some good data out of these pilots and be able to utilize that again going back to working together and how do we do that and get Cyndy's involvement and figure out how we make this something

that's important to patients because I think we all struggle with that right now.

MR. SERAFIN: No. I appreciate -- appreciate that, Al. So, Hudson, I want to turn to you. You know, you've heard a number of touchpoints discussing culture.

I'm really interested in your perspectives in terms of how culture of quality can be impacted by this program with your organization and also you think broader industry.

MR. GARRETT: Yeah. So I guess I'll look outside of my organization and think specifically about how can that culture then translate to better patient outcomes.

And part of it is registries, right? Registries make a lot of sense in different aspects. But I sort of see this program as kind of the trifecta of looking at the patient in the center, FDA is the regulatory body, the manufacturer, and really the healthcare community and how do we make sure they're all functioning together.

I think we've talked a lot today about the

FDA piece and the industry piece. The piece I haven't heard a lot about is how do we translate that into engagement with the patient.

And I think that's an opportunity that would be wise for us to focus on is maybe getting some patient advocates involved and saying, okay, how could we most effectively communicate this and what aspects of the cultural changes that we're going to make as an industry, meaning FDA and industry, would be important for us to communicate to you.

And I think that would bring a whole different perspective. And I think back to one of the first meetings I went to at the CDC where they -- all these leading scientists from around the world said this is what makes sense. And there was a woman in the audience and she raised her hand very politely and said, "What you're saying makes sense to scientists, but it will never, ever happen in a hospital in America."

And she now sits on the committee as the consumer representative. And I think that that perspective is valuable and I commend CDC for saying,

oh, crap, we kind of -- we sort of missed that one.

And I think there's an opportunity here to do that because we can make changes at the industry level. FDA is certainly making changes which is fantastic. But if we don't translate it down to every single patient bedside it's not going to meet the mission of what we're all trying to accomplish together so I think that's an opportunity we really need to talk about.

MR. SERAFIN: Yeah. Appreciate that, Hudson. Thank you for that. Robin, turning back to you. You know, you've talked about culture and the FDA. Any point you want to underscore?

MS. NEWMAN: So the quality journey that you all make in industry the agency's making a similar quality journey right now, too. So one of the fascinating things that I found when I got here was that Jeff said we were going to be ISO9001 certified.

I said, "We're not," you know? Because I -- because of my background that's what I -- I just assumed that we would do. But I will tell you it's really fascinating to watch this happen.

We have a contract with ASQ, we have dozens of people from my office alone who are now certified ASQ auditors or quality improvement specialists. This is a very big movement internally. So we're asking ourselves to do the same kinds of really significant changes that we're asking industry to do.

Now we're more of a service sort of organization. It's a little bit different. We don't build things. But the process and the journey is really not all that different in terms of understanding it.

So culturally what it's doing is really raising awareness on every level of why -- why are you doing that. Not just because you do it because you've always done it, but why are you doing that? How is that adding value to the process? How is that adding, you know, better assurances to the system?

And so we -- that question of and how does it add value is a very important one for us and we're asking it on every level. And I do feel the cultural shift occurring.

I mean, I will say when I got here a year

ago February it was different compliance. The Office of Compliance was a very different office than it feels like today. And my compliance colleagues I'm looking at them to see, but I felt it -- I felt like it was.

And it's because we've had this conversation on an ongoing and very upfront, transparent level for some time. And so this is really helping.

But I think the culture issue -- the other thing that we're doing to your point, Hudson, is we're spending time with patients. We're spending time with patient advocacy groups. We're doing direct patient engagement.

People at the agency I think a lot of times until a patient comes in and sits down and explains to you what it is that you do and how that im- -- or how what you do impacts their lives directly that's what makes it meaningful. And we're doing an awful lot of that kind of activity right now.

We will have we're hoping at least 90 percent of the -- of CDRH will have had at least one patient engagement by the end of this year. So we're

-- we've got a -- it's a pretty bold target, but we're on target to get there.

And I think it's a very, very important part of this step because tying all of it back to the patient and making sure patients understand what we're asking and that we're really soliciting their feedback in terms of their perspective on the value of this that's really critical here.

MR. SERAFIN: Yeah. Thank you, Robin. Joe, I want to circle back with you just building on what Robin was just talking about. From a firm perspective what's important to your firm with respect to the patient experience?

And then also can you describe, you know, some of the ways, you know, do you get feedback and, you know, the ways you'd want to get more feedback.

MR. FRIEDRICH: I mean, so there's the traditional mechanisms that we've received feedback. You know, the clinical studies, complaints, there are marketing surveys that are conducted.

The, to me, more novel approach I think is engaging more with patient advocacy groups, having

patients come speak directly with the company onsite about their experience and what goes through their mind when they're learning for the first time that they're going to get a medical device or they need one or the fact that the learned that they had some underlying condition that merited that.

We had a patient actually come and speak at that same summit I mentioned where she -- she actually is a member of our patient safety advisory board. She's on the -- she's on a number of patient advocate -- advocacy groups. And she's also very familiar with the industry and she happens to have one of our devices.

And what she shared with us was this graphic that she made that was what she called the stress rollercoaster. And it was kind of she walked us through all these different points that were peaks and valleys of the patient -- of her stress level based on, you know, learning she had a condition, learning she needed a device, getting the device implanted, you know, the follow up, learning that there was something that needed to be adjusted.

You know, just all of these different points where, you know, the mindset I would say we historically have had as a company is very much around, you know, the functionality and performance of the device, making sure that it lasts, you know, as intended through its device life.

And, you know, once it gets implanted successfully we're kind of like, you know, yes, there's the follow-up appointments that occur but we don't really think a lot about what is the patient actually going through and are we doing everything we can to make that experience as seamless and painless as possible. And for those patients who want to know more are we giving them access to the information that they deserve that's their data?

So I think there's a transformation that's occurring for us as there is probably for many. And I think that in having that more direct engagement with the patients between patients and companies, with industry groups, and with the FDA, as well, that -- that's something that we can definitely be doing a lot more of.

I think Cyndy mentioned a number of points around like the different types of patients. She brought up some similar -- some similar points. From her perspective she channeled the -- most patients want to -- at least from her experience most patients they receive the device and they want to go back to living their life. They want to forget it's there as much as possible. So anything that interrupts that was not a good thing in their -- in many of their view.

She did bring up there are those who want to know more and have access to information. There's so much technology available now than even five or ten years ago at our fingertips. What are we doing to make data more readily available?

And then she said -- and I wrote this down, but patients want to be respected and for us to respect their intelligence and their experience. And to not kind of forget that whenever -- especially there's an issue that occurs are we taking into account their voice in how we go about communicating, how we go about handling that whole process.

So it just opened a lot of eyes for us. It made sense, right? It was kind of like, duh, of course if you're in that -- if you're in their position that's probably what you would channel. But you kind of get in this I would say scientific technology mindset that doesn't necessarily put kind of that empathy glass on first so, you know.

MR. SERAFIN: Great, Joe. Appreciate that. So we have a couple minutes left. I see my little yellow light so I did want to open it up to the audience. Any questions you have for the panel?

MR. GARRETT: And I just want to add one thing while we're waiting for questions. I think when Robin spoke this morning my red alarm went off and it was the first time that at least I saw the alignment of FDA with that halter (phonetic) blame experience piece.

So, you know, the mission that you so eloquently articulated is really the definition of population health management. Now what we're trying to do is overlay that with the patient experience and taking costs, maybe it's time, maybe it's efficiency,

maybe it's beat the market out of the system.

And I think that's a huge marketable piece for companies to be able to go forward with, you know, in collaboration with the FDA. And it's just a buzz word right now in industry that I really think it's, you know, kudos to the FDA for kind of aligning everything so that the stars align with that.

MR. SERAFIN: Yeah. Thank you, Hudson. Luann, you had a question?

MS. PENDY: Yes, I do. Al, I'm going to pick on you. So last week Al and I were on a panel with Cyndy and Robin to talk about this program at MDIC. And Al sent us a note afterwards unbeknownst to us his CEO was in the audience as we were speaking. So and you said thank you to us for the work that we had done.

Could you tell us real quickly what were the key points that your CEO took away from the discussion?

MR. CROUSE: I think a lot of the same things that we've been talking about up here, you know, there's very few of the other programs that

we've talked about today the MDSAP and the other compliance measures that are actually after making the product better.

So, you know, I think that rang true to him as this is one of the few things out there really designed to improve the product. I think, you know, the other things that he was very interested in was our collaboration with the FDA, building a better relationship.

And there was some talk in that panel, as well. One of the other possible advantages to this if we figure out how to roll up the, you know, overall scorecard of what we're doing possibility for us as a potential merger target or an acquisition target that may be something that that would be beneficial, that people would see us leading out there and saying we know they have a good quality.

We've all seen mergers that have gone badly awry when you finally incorporate the product into the company and you find out that there's a lot of hidden skeletons in the closet so.

MR. SERAFIN: Thank you, Al. Steve?

MALE SPEAKER: It seems that there's a lot of alignment among the panel that patient engagement and education is critical. In thinking about the pilot program, though, that we're discussing today it seems like as well at least for the next year plus it's not going to directly serve that end.

Because, as we've been discussing, it takes a group of participating companies and determines where they are in terms of their quality maturity and then tracks their progress over time hopefully to demonstrate that they're improving.

That doesn't directly translate into helping patients to understand and make decisions about the quality of the products that those companies are producing. That doesn't mean that the pilot program isn't critical. It is.

But it raises the question, then, does the interaction with patients occur as an activity of the steering committee that is integrated over time, is it occurring more so through other initiatives like the analytics program that's ongoing, or do we need to broaden the scope of our thinking to talk not just

about influencing patient decisions, but also provider decisions who may be more ready more quickly to receive the kind of output information that's coming from the pilot program.

MR. SERAFIM: All right. So thank you, Steve. I'll jump and say, D, all of the above is I think where we all want to go. It's -- you know, I think all your points are spot on and well taken and have been brought up on all the different venues around the Case for Quality.

And, again, it's that kind of crawl, crawl, walk, run scenario that we have here that we're all learning together. I think the key is to just underscore one point you made, I mean, you've here loud and clear is the fact that the center the patient.

So we have to -- we have to have that begin with the end in mind mentality and how we can bring that long, you know, through everything. Last mention I'll say is that also, you know, we were joking before earlier.

A lot of the maturity model folks we were

just talking about like, you know, the first time we started going down this road everything to be perfect. We were all -- and Al knows this and Robin and everybody's like we want to be perfect.

And we kind of went round and round the axle for a couple of months really where we had a lot of effort and we just everything had to be -- you know, get a bunch of quality people and FDA in a room what do you expect, right?

But I think we finally took it back a couple of notches and said we can learn, use this as a learning process. And everyone became more comfortable with it.

So I think it's that eyes open principle that I think we've adopted and now been able to put into action and having MDIC as a great forum for us of collaboration that we can be mindful of that.

I think we have time for one more question. I know we're a bit over.

MR. MAZURKIEWICZ: Hi. My name's Andrew Mazurkiewicz. I'm from Edwards Lifesciences. And I worked in a technical support group that received

patient and healthcare provider calls.

And so I have -- I have some really close ties to patient information. And we get what we'd call shoppers where maybe a patient or a patient's family member would call in. And we were very careful about what we told our customers what was approved to say to your customer or patient. So like durability. It was very vague what we gave them.

So -- so my question is when it really gets down to the information we're providing and what's cleared and approved is there any thought from an FDA perspective on improving that process so that we get information out quicker?

MS. NEWMAN: So if this works the way we think it will we should be able to do that. I mean, one of the reasons that you were vague is because your quality system was not mature enough probably to actually measure that in a reliable manner. And so you were afraid to make, you know, certain representations --

MR. MAZURKIEWICZ: Right.

MS. NEWMAN: -- if you couldn't really back

that up with a really robust, you know, quality system. So I think that this is one of those things that if we -- as we build it it will come.

So the more mature the system is the more reliable the system, itself, is higher fidelity, higher quality the more likely it is then that you -- when that question comes up you'll have real data --

MR. MAZURKIEWICZ: Right.

MS. NEWMAN: -- that sits -- that you can rely on. In terms of the agency I don't -- I can't really speculate, maybe my colleagues could, on how we might change, you know, what we say and things like that at this point.

But I want to keep my mind open and I want us all to do that to what the possibilities are in terms of what kinds of things can change. So we've tried hard to do that through this process and we will continue to do so.

MR. VINCENTY: So just to add to what Robin's saying, right. This is the starting point, right. We are talking the crawl, walk, run. There is a lot of other efforts that are going on within the

center. Part of a larger vision that I think Dr. Shuren had shared at times where we start to incorporate and leverage a lot more of that real world evidence. The real world data.

All that information that's gathered that rich set that you probably already have as companies how do we start shifting the mindset and making that a little bit more available publicly so that that can happen at a faster pace.

Baby steps. We start getting the process in, we start, you know, taking some things in stride here first and then we get to that point.

FEMALE SPEAKER: I just want to add to that. I know you're not taking other questions for time reasons.

MR. SERAFIN: No.

FEMALE SPEAKER: But --

MR. SERAFIN: (Indiscernible.)

FEMALE SPEAKER: Yeah. Going back to the questions on what can you say, I guess are you revisiting them? Because then you have to be careful with the promotion and advertising, labeling claims.

And even if it's data that you have internally it may not -- it may be looked at as promotion and advertising. So I think that's maybe something to think about because I know as being involved in the Case for Quality for years no one's touched on that yet so.

MS. NEWMAN: But, Monica, that's why I said I'm not sure what I would promise to do on that right now. But I do think the more reliable the data, the more likely it is that it'll be something that we can feel comfortable with in terms of what we would approve, say, for your promotional labeling.

So it's all kind of related in that way. And I would tell you just in final kind of summary for me what you want -- I think -- and Cisco's alluding to this.

All of these things touch on each other. So Case for Quality, what we're doing in our patient engagement, what we're doing in NEST and the development of, you know, the neural network, if you will, of all this patient information, all of these things are related to each other in the sense that

they all help us get a little closer to the truth, whatever the truth is as it's experienced by patients.

And once we really understand that then I think we'll have a much more robust process all the way around.

MR. SERAFIN: Okay. So with that I'd like to thank your panel for your thoughts, your insights, and your messages. Thank you.

(Applause.)

MR. VINCENTY: So I want to thank everybody who participated in the panel and offered some great insights.

Next I'd like to introduce Erin Keith. She's our -- she's actually our TPLC project lead here for Office Device Evaluation. And she's going to moderate the next panel and I think she's making her way up now.

(Applause.)

MS. KEITH: I feel really tall all the sudden. I think it's on. Okay. There we go. Red means on, not off.

All right. Good afternoon, everybody.

Thank you for sticking with us. I know it's -- it's, what, it's 2:30 now. Wow.

So this afternoon we're going to talk about and talk through some of the risks associated with -- with doing this pilot and potentially some mitigation strategies for those.

And with us today we have Pat Baird, the head of Global Software Standards for Phillips which is not on here, Al Crouse, George Zack, Cindy Winfrey -- everybody up here -- Cisco, Emily Miner, and Kimberly Kaplan. And I have my crib sheet so I'd like to thank everybody for helping me out on that.

We're going to sort of talk through some of the likely risks associated with starting any new program. And those program -- those risks often align around a couple of different categories.

The effective communication around that program and therefore the perceptions that people have about that program, operational concerns people would have about how we'd actually go about doing it and managing con- -- and in controlling that process, and then general risks and concerns associated with the

outcome.

What would success look like? What -- what happens when the real world intrudes and a negative patient event happens? How -- how would we make this cost effective for small companies?

So we'll start off with the perception issues. And the previous group had a really great conversation around the concept of what's in it for me, what's in it for my company, my organization if we participate.

And I wanted to ask if there was anybody else on the panel who had any additional thoughts on that. If Pat or Emily or Cindy had thoughts in relationship to what's in it for my organization to participate in this particular pilot.

We're good here?

MALE SPEAKER: Yeah, we are.

MS. KEITH: Thank you. Not a lot different than what was previously said I don't think. I think for us in particular it's the inspectional opportunities that we would have related to the program, but not a lot different than what was

previously said.

FEMALE SPEAKER: I would agree. I think what I'm going to take away from this is probably a conversation to take back to my company on the way I'll phrase it would be the cost of complacency. In other words, if we continue to do things the exact same that we're doing them today is that really in our best interest?

MR. BAIRD: Hi, this is Pat. I had a couple additional thoughts. I had been thinking about this, you know, before this meeting and it raised some concerns in the past.

Certainly I think that it's an easier sell when it comes to PMA style products, right? And I think that we had lots of examples of that. It was nice I think Robin earlier was saying that like 510K's still a work in progress.

So the fact that it's a work in progress to me was good news. It's not just this is for PMA folks. Everyone else good luck. That, you know, knowing that there's some work in progress that's going to help.

It also dawned on me as I was thinking of all the different products I've supported in the past that you know there's going to be some product line, some manufacturing centers, some design centers where this just isn't ever going to be -- when it comes to an ROI something for them to focus on, right?

There was so many other things going on and so many other investment opportunities in my head I had to convince myself we can't be all things to all people, right, and all types of products. And so if this ends up being only a win for PMA, that's still good. That's still, you know, a good step forward, right? We should be proud of that.

But then what I also started thinking of some of the concerns that I had I saw were addressed in different slides and some of the different presenters this morning. And so I thought -- I started thinking of, well, how would I sell this to my C-suite?

When I'm talking to, you know, the upper echelons I need to talk in a different way. And so I'm wondering if there would be value in like a one-

page C-suite what's in it for them, what's in it for the business style sell sheet, right.

And to me that's also a totally different audience than when it goes to implementation and we're talking about some of the traditional compliance folks, traditional quality the guys that used to run our audits and inspections. So it's a totally different world for them I was thinking maybe there's a different FAQ, a different something written just for them saying this is how it's different than MDSAP, this is how it's different than all of the inspections you've had in the past 30 years that you're used to front room and back room.

I'm wondering if it would make sense to I don't want to say parcel out the messaging, but fine tune the messaging a bit for the different audiences that we need to take and sell on this.

One thing I was thinking this morning when there was the talk about the handbooks for the assessors. I'm wondering if an excerpt can be pulled out of that handbook to share with folks because I can't see going in and saying, oh, hey, boss, I need

you to write a $35,000 check. Some folks that aren't FDA employees are going to come in and start asking a bunch of questions.

I don't know what questions they're going to ask. They're just going to start asking questions. And, you know, it might save us money in the future. Yeah. I can't do that sell.

Having a couple of examples of what those questions are or the kinds of things that they're doing, yeah. You know, this is also why I'm not in sales, right.

So I'm thinking that there's a couple things that you probably have the raw material for that maybe we could put together that would help package this nicely and sell it.

FEMALE SPEAKER: Just another point based on what you just said. I think one of the things I learned today that could also maybe be part of that it's starting to become clear with this program how we bridge the gap between that compliance mindset where a C-suite person maybe can't bridge the gap between how that translates to quality as a competitive advantage

and this starts to bridge that gap and talk about it in a different way.

And that could be a pretty significant benefit and a way to sell this to anybody, including the C-suite I think.

MS. KEITH: So earlier today we had some presentations that talked a little bit about how this program is a little bit different from traditional compliance auditor, you QSIP inspection, or the MDSAP or (indiscernible) audit programs that currently exist now.

But those are the things that companies are used to. People that's what they do, that's what they know, that's what they're comfortable with. It's how their systems are set up.

How does this program we have now that we're trying to pilot here and have held many stages in the last year make use of a company's existing quality system information and risk management programs so that this isn't a rebuild from the ground up for them?

That they understand how they can take things that they do now and put them into this pro- --

into this pilot.

MR. CROUSE: I'd be happy to try and address that. I think the crux of the assessment that's done is more of a conversational model around how your quality system is working.

So the initial intent isn't to particularly direct you to be changing things prior to this conversation taking place. It's really to have that conversation to identify what portions of your quality system are strong and what portions could possibly take some improvement.

So, you know, the real sense as well is to see how cross functionally that quality system is working. As I'm sure even in a small organization like ours we only have about 40 people in the Minneapolis office, but we find different groups are much clearer on how the quality systems intended to work than others sometimes.

So I think, you know, just sharing that information sometimes is a good insight to the quality management of which groups are getting it and which aren't and where maybe we need to spend some more

time, you know, with the culture bringing it up to speed.

MS. KEITH: George, I saw you shaking your head. Did you want to add anything?

MR. ZACK: I wanted to hear from Al because Al has -- can speak from an industry perspective and having gone through one of these assessments, one of these appraisals as well as obviously sitting across the table from the FDA.

There -- as Al said, the nature of this appraisal as to how we're approaching it it will be initially conversation based. Certainly there is going to be when there's opportunity appropriately to look at some documentation to support some of the things -- some of the areas that we're looking at. We will certainly also look at those.

But I would say it's different from an audit. We're not sending a list of, hey, these -- we need to see your ASL, your DHF, and evidence of your CAPA list to start.

We know everybody can produce that, right. That's just the basic compliance perspective. So it's

really beyond just that documentation existing it's understanding as to how is the quality system effective, how are what you're actually doing with your practices, your processes, how your capabilities are impacting the quality of your products.

MS. KEITH: Cisco?

MR. VINCENTY: So if I can add just another piece to all of that. One of the things that we saw when we did the proof of concept and Al was gracious enough to let us kind of sit in and watch what was going on there. What we've learned as an agency about the model and the maturity approach is it's really agnostic to your quality system.

So it's not asking you to reinvent the wheel. It's really going in there and the way I've kind of learned to accept it for myself is these practices they're just the result that happens when things are executing well at certain levels, right.

You see these things in place. And that's really what the appraisers are going to go in there and look for are these things in place. And if they are the system you've developed which is required by

law to be, you know, QSR compliant, that's what we're working with, that's already foundationally built in, right.

They just come in what are your original stakeholder needs of which your regulatory bodies a stakeholder and that's where you start. So the idea that it's a kind of reinvent and everything else it was very easy -- well, I'm not going to say very easy.

It took a little bit of -- of time to go through the process and seeing what's going on to really get the crux of what was happening there. And not that we needed to remap or reinvent how things were, it's just let the practices really be what they are.

You quality system executes. Let's now find out how many of them are really are meeting the right levels.

MS. KEITH: Thank you. Robin made a comment about -- earlier today about how this is really continuous process improvement and quality. And that they've -- that the Office of Compliance has heard concerns that they're worried about compliance getting

watered down in this process and maybe leaving a company vulnerable to a regulatory problem or problem with a regulator somewhere in the world.

And it's one thing to hear Robin say that that that's not a problem. So I wanted to try and get the industry's perspective on how they see that. Do they see that compliance gets watered down by this process and either -- and also maybe George or Kim could maybe chime in from what they've seen with other industries that maybe have regulatory component and if they've ever seen a clash between those, you know, meeting the -- being successful in CMMI and then not being successful from a regulatory perspective.

MR. ZACK: So I guess I'll start on this end. I think you may all recall it was one of the third -- the third or fourth slide that we had in our presentation of the industries, the organizations, the companies that have been involved in leveraging CMMI over the last -- last decade plus.

They have regulatory obligations -- automotive, aerospace. This is actually -- this CMMI model has actually been leveraged in health IT and by

some device organizations. There's a device organization that achieved CMMI Level 5 while still being 820 compliant, held a 13485 certificate. There was no clash.

So as far as I'm aware these attributes, these descriptions of the processes and the practices in CMMI have yet to clash with any industry regulations anywhere. If anything, they can be leveraged to further -- and Cisco said very well there. They can be leveraged to support your quality system, your regulatory requirements. You're identifying the needs of your stakeholders one of which is your regulatory stakeholder.

MR. CROUSE: In the pre-pilot assessment one of the survey questions that was asked at the end of all participants was does this in any way conflict with the compliance aspects.

And I think it was the on- -- well, I know it was the only question that got answered 100 percent everybody agreed with that that it doesn't make any impact on that.

And as Robin pointed out in her slides

earlier today, it's part of the reason for the expectation that FDA setup up front that only people with a good inspectional experience in the last five years with FDA would be eligible for the pilot.

Again, we may be able to look at that in the future and see, you know, how to work around certain situations that may make sense to work around. But I certainly don't see any reason why it's in conflict with the general compliance aspects.

MS. KEITH: One of the -- being a regulator I've worked at the FDA for longer than I want to admit right now. One of the reoccurring themes we hear from industry is the desire for consistency and to ensure that there isn't -- that we take out a -- the subjective from all of our processes and that we try to be as consistent as possible so that industry knows what to expect and when to expect it.

And so could I get the aud- -- the panel to discuss perhaps how they see that this program can control for variation in the assessors and making sure that the assessments themselves are not purely subjective?

MS. KAPLAN: Sure. So I already spent quite a bit of time sort of talking about this, but I can again speak to it. We have a number of documents in place that provide very strict guidelines and expectations for how operations are supposed to be performed as well as how the appraisal itself is intended to be performed.

We have very strict standardized training for each of our assessors. We make sure that they bring a certain level of medical device experience. We make sure that there are at least two of them on each appraisal to eliminate the subjectivity that can come from a single person.

These teams aren't necessarily always going to be the same group of two people so it helps to -- for each team -- each person gets to keep the other person in check and make sure that they're following the guidelines as intended.

MR. BAIRD: I had noticed that slide early on and like started my notes. And like to me that slide is one of those great things for that sell sheet, for that compliance officer's objections sheet

of saying, look, we're doing this, we're doing this, we're doing this, we're doing this, we're doing this. What else would you like us to do to try to get these guys as objective as possible?

We have five different considerations in this. We've thought this through. I thought that that made a very compelling argument.

MS. KAPLAN: Thanks. And actually you just reminded me and after all of that is said and done we still put each of these appraisals through a quality review check to make sure that they were, in fact, done consistently against the plan we had in place.

MS. KEITH: Cindy, did you have something?

MS. WINFREY: I was just going to articulate that, you know, I thought, Kim, you did a really nice job this morning of outlining that. And it was an assurance to me that it's a well thought out process and it has lots of checks and balances.

I think that's -- that would be easy to explain. I do like the idea of a cheat sheet that you could then share with your leadership.

MS. KEITH: So one of the other -- oh,

sorry.

MS. KAPLAN: Yeah. I was just going to share an interaction I had actually with Cisco last week. You know, in talking about some of the inconsistencies maybe that have been experienced and that concern just putting it on the table.

Part of the discussion in addition to what the panel members have shared Cisco helped share as well, you know, the engagement can be had with the agency as well to share if there's an inconsistency in experience and how that back and forth process would work.

And it really, you know, took some of the scare out of the -- out of the inconsistency that's been experienced and some of the concern that practically we would have if that happened in engaging with FDA.

And so that's probably another area if there were to be inconsistencies that there's -- seems like there's a mechanism on the back end as well to cover for that.

MS. KEITH: So stuff happens, you know, life

happens no matter what your great plan. No one's perfect. No one knows everything. You can be, you know, follow your plan perfectly and then, you know, the universe throws you -- throws a flag on the field and you've got a problem.

So if a company is participating in this program and a problem arises in the post-market from -- or post the initial participation so there's a perception that the performance metrics have a problem or that there -- have a decrease in a category that they've been evaluated on as they're participating in this and that they're reporting back on.

What does that mean to a company? How should they then engage with the FDA or CMMI in dealing with that situation or does that suddenly mean that they're no longer able to participate in this because everything didn't go perfectly?

MR. VINCENTY: So I can start. Just from the FDA perspective, the -- the premise around this is built around that engagement piece. So Sean mentioned it during our rules of engagement piece, the key there is going to be early engagement, communication, and

we're committed to try to work through what the process because it's part of the learning I think that we've got to do on our end.

But, you know, for example, on the metrics side I could tell you that we don't really know what we're going to expect when we start gathering and collecting those metrics over time.

It may be that some situations it looks like there's an increase, others are static. And it may be the one that's increasing that's performing better because they're identifying more of these issues and moving them up front.

That then becomes an opportunity to say, hey, not that we're looking to enforce, but maybe this is something that we share across an industry, right. Here's how a high performer identifies additional issues. Here's where we see them really targeting and moving the shift towards the -- you know, moving more towards the left early in the design stages.

It could be that, you know, we see a manufacturer who knocks it out of the park in terms of all the stuff gets identified early and not at the

end. Again, that becomes a good example.

The idea here is -- and we've done this through some of the engagements to begin with -- is where are the opportunities not just from an FDA standpoint to monitor, to see what's happening, where are the opportunities for you guys to kind of teach each other, share amongst your learnings, your capabilities, you know.

It's often happened in some of these interactions where somebody has come up and shared their experience. I don't know about it until much later. Someone else from another company reaches out to them and says, hey, can you come and share what you guys did with us and they completely change the dynamic on what's happening there.

To me that's an ideal engagement. That's not us, FDA, telling you what to do. That's, again, everybody's learning from each other what are the practices that worked.

So there is the expectation that's going to happen. Being able to respond to it that's always going to be the key and that's really what I think we

want to emphasize throughout all of this. It's enough to identify.

We can take a lot of leeway in terms of what we're seeing as we understand what's happening, but if an actual issue does occur let's both as an agency, as an industry let's all get on top of it, let's figure out what the best path forward to resolution is.

Focus on that solution first, everything else we'll figure out how to manage and learn from from there.

MS. KAPLAN: Yeah. I just want to reiterate Cisco's point that it is all about continuously engaging as we run into potential issues, which this is a pilot so it might happen. And sometimes we will see that. Sometimes you've got to slow down to speed up, so we may see some of those metrics come down before they come back up and that's perfectly normal as long as, again, we continue to have those conversations and determine why that happened, you know.

If something goes down we want to ask why, if something goes up we also want to ask why, right,

how do we make that repeatable? And regarding any other issues we might see in the marketplace, again, hopefully as we move through the pilot we can help your organization to improve its capability to then bounce back from things like that.

MR. ZACK: So if there was hypothetically an issue with Al's organization CDRX --

MR. CROUSE: Hypothetical is correct.

MR. ZACK: Hypothetical. We're already at a place where this is going to be a much easier conversation between the agency and CDRX because of the relationship that they've built through MDIC, through this program, and that would be obviously true for any of the participants in this pilot program. You're starting to build that particular trust between the agency and your organization.

I also think that the point that Cisco made I've actually seen this in action where we were working with a very large company and performing CMMI appraisals across that organization as well as helping them with their quality system.

And we tried to initially share that data

with the groups in- -- it was a lot of little companies inside a large company. And interestingly when they first started there was very little interest in sharing that information -- arms crossed, please don't tell anybody else what problems we had, what findings that we had.

And over time it became very much instead a sharing culture where it was how did you fix that? I'd like to hear your input on what's working well for you. I really think that once we get a body of appraisals going here in this pilot program the participants are going to be interested in understanding the common strengths, common concerns, special -- special weaknesses, if you will, ones that are one offs and how other organizations are addressing that.

And I think we -- without -- without, you know, trading any IP you can share best practices, lessons learned as to how to improve your organization and the culture of participants. I think that's really -- that's also a side benefit that I think is going to be huge as an outcome of this pilot program.

MR. BAIRD: So I'd actually like to add onto that theme. I think, Robin, you had the slide with the silos, right, about some of the earlier days of this initiative. And one of the silos was a competency development.

And the idea was we were looking into the future saying, okay, we're going to eventually get to a point where we have these nice assessments that say here are places to improve, here are places to improve.

Well, okay, but how are we going to approve? We can hire George to come in and -- but he's only bandwidth limited so much so there can only be so many Georges. How else can we take and help out?

And so I figured this was a question that might come up later. I didn't expect it to come up this early in the conversation. But I think it's going to be kind of up to us as a community to say how is it we're going to take and share those best practices.

Are we going to use some of the existing trade associations that we've already done the Mida,

the AME, the AdvaMeds of the world? The AdvaMed has a library of best practices.

We've shared some as part of this competency group one of the first papers that we wrote. And it was different companies getting together sharing their experiences. Not saying this is the way you must do it, but, hey, collectively we found when we tried to do it this way it worked better than when we tried to do it that way. And no matter what you try here's three things that are going to be kind of thorny issues for you to have to deal with.

So very pragmatic, very practical. But the first thing that we picked on was the cost of poor quality. And I think, Luann, you had mentioned that earlier on how is it we get the conversation going? How do we show those invisible things and make those things visible to management so that we can make the case to invest in these things?

Another paper that we did, again, sharing practices across, not saying this is the only way to do it, but was management review, right. How do we get C-suite to see what's really going on in the rest

of the company and move away from what I called management review theater which is where you have a meeting called management review and they're costumes and there's a script and it's all preprinted and there's meeting minutes and they're signed off. And we did them every quarter, but it's not real. That, you know, nothing really happens.

Move towards what Joe Sapiente (phonetic) had called endoscopic management review. And so far I have never had to explain what was meant by that adjective, let me phrase it that way.

So anyway, I think that something to be -- we have to figure out collectively in the future is what's that information sharing, how is it we can take and get that peer-to-peer therapy sometimes when it comes to these things.

MS. KEITH: So I was hoping to get industry's perspective on -- so this is Pat, Al, Cindy, Emily -- what you all think are the risk to companies that participate in this pilot and what are the risks to companies that don't participate in this pilot?

MR. CROUSE: I guess I'll start off. I've thought a fair amount of this -- about this as we've been working on developing the whole thing. And I would just like to say I don't think there's any real risk to companies either participating or not participating.

When you look at the whole outset of what we were targeting to do is we're targeting to bring up the quality of the whole medical device industry. And part of that is utilization of resources both at our industry companies and also at FDA, as was pointed out by most of the FDA members this morning.

So the bottom line is that if the FDA is spending less time out there looking at places that are actually doing a good job it frees up those resources to be doing inspections. And these aren't punitive inspections, but to be helping to identify places where there are recalls out there ready to be happening that they can help those groups work through that.

Again, I think in developing a more collaborative relationship between industry and FDA we

bring up the whole industry. So I don't think there's any risk.

And, you know, there's been some questions I know about, well, if FDA's spending time looking at this they're not going to be spending time on my inspection or my inspections going to push to the end of the line.

No. It actually should move your inspection up because they're not going to be out at all these other places inspecting things where there's no problem. So just my perspective.

MS. WINFREY: I would agree with what Al said. I don't really see a risk to this myself. I only see a benefit. I really like the concept of trustworthiness. I like the concept of the safe space. I love the opportunity to have a dialogue and a conversation so that you're on the same page and you're headed towards the same direction.

So I only see the positives in this. I can -- I can understand people's fearfulness or their lack of understanding of what the processes and how they differ, but I really only see a benefit.

MS. MINER: So I'll echo the comments that Cindy and Al have made, but I do see it's not so much risk and participation or not participation. I think from what I've learned the risk is in how we execute the participation itself and how we ensure that we get over the fear of transparency, we get over the way we've always done things, and we avoid losing compliance for the sake of this program those kinds of things. That's where I see the risk that together we'll have to navigate.

It sounds like those things are on the table which is the first part of the battle so I'm very encouraged about that. But as I think about risk it's not about participating. It seems like a no brainer. It's more about how to participate in a way that's best for all of us. So that's where my focus will be.

MR. BAIRD: The two things I think I was worried about the most and I think that they've been addressed just in the discussions here. One, I'm thinking, oh, we did an internal quality improvement something, we put our sales rep through training just to make sure they can recognize what a complaint

really is and they know when they need to take and file things, and, oh, look, in third quarter we have a spike in the number of complaints.

And suddenly, you know, that looks really, really bad that something bad happened the third quarter. The product quality dropped. Well, no. Actually we have a better measurement system now.

And, like you said, having -- being able to have that dialogue, right, rather than let's just be quiet and hope no one notices, right, that there was a spike that quarter.

The other thing and I think that it's covered in the sort of annual pulse updates or six months or however often it is was I'm concerned about mergers and acquisitions and spinoffs. But not only those, but also my experience in the past had been when I get a new executive all of the procedures have to change.

Whatever's centralized needs to be decentralized unless it's the next guy who centralizes the decentralized things. And so the execution of the procedure there's been no merger, there's been no

acquisition but all of my procedures have changed, all of my -- am I still executing to the same thing? Does this require a new reassessment? This just isn't going to make sense.

I think that if I'm understanding that period pulse update and how that is we change all kinds of things in the background, but so long as we're still, you know, working on those things that we talked about I'm getting the feel good.

But, again, articulating those circumstances I think would be critical.

MS. KEITH: So many of you are very well aware of the fact that the medical device industry has a large percentage of small businesses. And I mean by that by the, you know, government definition of small business. And the definition (indiscernible) chooses when we set user fees and what you have to tell us if you'd like the small business discount.

This is -- this is something that has -- potentially has a cost associated with it and then a benefit associated with it that could offset those costs.

And so how do we make this cost value proposition work for small companies? What do we do that makes it affordable and enticing for them? And do you see there is a difference between what needs to be done for the small businesses versus the large businesses?

And I'm happy to have George or Kim -- Kim answer this or anybody from the -- from industry that has insight into this.

MR. CROUSE: I'll start out with my opinion because I have a fairly strong opinion on this. It definitely is one of the bigger struggles I see with this is just, you know, convincing small companies that the cost is worth it.

Listening in this morning to some of the structures we've set in place for this I think there's some possibilities of working with CMMI and FDA in figuring out a way to reduce those costs. I've actually got some good ideas in mind that I haven't talked with George and Kim about, but I was going to hit them up right after this with.

But I think the big push for small companies

is this is a way to go out and compare yourself to others in the industry and say what you're, you know, going to be able to do.

And, you know, for a lot of the big companies having a major quality recall isn't -- isn't insignificant. I mean, you heard the larger companies talk about the amount of money they spend. But for small companies spending that much money and getting a black eye for quality with one of your only products you're going to be out of business.

So there's definitely a huge payback that maybe isn't so much with the large companies that's the reason for doing it. But I need think we need to figure sort of like we've done with MDUFA and things like that of how do we scale that for small, medium, and large size companies. So the larger companies help pay the way of the smaller companies if that makes sense to do.

MS. KAPLAN: Yeah. You pretty much took the worlds out of my mouth. I mentioned this a little bit earlier, but one of the things that we're learning a lot about is what is going to influence the cost and

what does the cost look like and what are we able to provide for that cost.

And, again, it's a learning process. One of the things we're trying to look at now is exactly as you mentioned a tiered system for small, medium, and large organizations basing that off of MDIC and FDA's tiers and seeing which makes the most sense for this program.

And, of course, having those discussions with you provide great value. Thank you.

MS. KEITH: So my last question is how would you define success for this pilot? And I think that there are a lot of different perspectives at this table that should be heard from so if we could maybe start down at the end with George and we'll work our way back.

MR. ZACK: I was just discussing this at the tail of lunch with a few folk. There's obviously some very basic measures of success. We heard -- we heard it from Captain Boyd about executing the 30. That certainly is a goal.

But I think what's a little harder is to say

how do you measure that we've done enough effective learning from the execution of those 30 to then say that we've had -- we're going to have a successful program and one that we can institutionalize into the agency and to the industry into 2019 and beyond.

My perspective is beyond just the execution of those appraisals I feel an obligation to the close measure of success is asking the Al's, the Pat's, the participants in the program did you get some value out of this.

When you got your feedback from your appraisal was there feedback in there that helped drive your capabilities in a positive direction to improve the quality of your products?

And I know it sounds maybe cliché, but if that's what's happening then from perspective that's successful and maybe it's success by each particular organization.

I also think that as we alluded to in some of the earlier conversations I think that if we see a community of the participants beginning to share, again, something that's hard to measure from a success

perspective, but I think if you -- we can look at that and we can see CDRX and other organizations sharing what they've learned from their appraisals, best practices, areas of concerns and how to address that, I think that's also an area of success that I'd like to see by the tail of this particular pilot.

MS. KAPLAN: Just to add to that I think you touched on all the things I would want to say. But just going about sort of how do we measure that? Well, we're looking at how many people have enrolled. Out of the people who've enrolled how many people have executed the appraisal, out of that what did the results look like, how do those trends continue throughout the year at the checkpoint processes, how do those self-reported metrics of how the organization itself measures its level of quality how did those change over time.

We will be sending out post-appraisal surveys to all organizations who participate to see how they felt about the survey, asking specific questions like what value did you see out of this, you know, how was this compared to some of the other

experiences you've had with an audit for example.

So we'll be sending out those surveys as well.

MR. VINCENTY: So it's interesting because I think the teams have done a lot of work in terms of defining, you know, what kind of measures are we going to be looking at and really monitoring over time to see what needs to be adjusted.

But I think from at least my standpoint one thing that I would say would be, you know, a couple fold. We've got the industry perspective, the program perspective, what would be its measure of success.

I'd like to actually see at this point in time after the pilots over that we have proven that a different form of engagement by providing that positive feedback that that activity actually does drive a better focused improvement action at a manufacturer.

We've seen some early stages in some of the proof of concepts so it's the potentials there. So I'd like to see that the program demonstrates that there's more of that happening and it goes into an

operational standpoint. That's big.

And then from an FDA standpoint because I keep saying, you know, we're doing this for industry, but we've also got our piece of it, too. You know, we've got a lot of very, very capable people.

I'd like to have them solving some of the other problems that we deal with. I'd like to have them, you know, maybe figuring out if throughout the pilot we learn that there's an overall industry trend -- and this is something Luann's gone -- but we've talked about a few times, you know. Is CAPA being approached the right way and is there a bigger activity that needs to happen around CAPA as a system?

I'd love to have people dedicated to that and then freeing up the resources from our reviews, some of the ones that we're looking at right now, are being done showing that we can look at things differently here at the agency. And being able to prove that it still provides the right value, it still provides the right level of oversight and it makes things easier on both sides.

To me that's a measure of success.

Everything else that happens along the way if we need to adjust, that's adjustable. But, you know, demonstrating that, you know, we can actually impact how we do things and refocus our resources and then demonstrating that that same occurrence happens in industry I think that's what I would be looking to see to make a case for maybe operationalizing what needs to happen at the end of the year.

MR. CROUSE: I think most of the short-term objectives have already been talked about. I think those are the main things that are going to show whether we've been successful.

But I do think just, you know, sort of anecdotally a couple of other things. Just the working relationship that we as industry have with FDA and the trust build there I think and then figuring out how we translate that as we talked about back to the patients, how do we get the patient involvement here is going to be important in how we continue to drive this forward.

And just on sort of a personal anecdotal level we're looking at doing the -- we did the pre-

pilot and we're looking at doing the pilot later this year. And I was just looking last week at times that were available.

And we have one of our management people who generally doesn't see a lot of value in audits. And when I asked everybody what they were -- when they would be available I was looking for two to three weeks and he said, "I'd be available any of those times. I'm looking forward to it."

And I never thought I would hear that from him so it's already successful in my book.

MS. MINER: I'll echo what everyone else said, but maybe go a step further. Cisco mentioned, you know, wanting to make sure the program is successful from a -- you know, are we getting the information that we've asked for. Al mentioned are we -- are we able to impact the patient in a positive way.

I'm also looking to see that this can help foster innovation. I think some of what folks have touched on today is that we -- the perceived cost of compliance or the actual cost of compliance is

sometimes driving firms not to make changes or to do things in a positive way.

And I think if we do this right we can get to that place. So, you know, even taking it a step further that would be an important benefit.

MS. WINFREY: I, too, would echo everything everyone else has said. I do like the idea of increasing innovation. And I ultimately would like to see the trust improve in the patient population. Their trust in industry, the faith that they would have that we would tell them the truth and that when we give them a product it does what it says it's going to do without potential harm for them.

MR. BAIRD: So now I'm stuck because I don't usually go along with the crowd. And so if I say that I agree with them, right, and I'm the last one so I just can't go there so I'm just going to set that aside there.

There are a couple things that I had thought of and I do worry about with this. This panel, this audience, right, we're a self-selected group, right, that showed up here. We're inclined to get along. A

couple people are curious and want some regulatory intelligence to take back home, but I think, you know, largely this is a kumbaya kind of group.

The folks that didn't attend are I think some of the stakeholders that we're going to have to take and manage. And that's why some of the sell sheet stuff.

But I still have a concern about that so I don't know if folks have talked about -- I haven't heard it mentioned much, but have we thought about going back to the original barriers paper back in 2011 and take a look at the data that was done then, the data that we could collect now. Can we validate this initiative? And maybe at the end of the pilot wouldn't be enough time.

But to me I always envision this was started by the barriers paper. Let's go back and see are the steps that we're taking going to address those issues that were brought up in the barriers paper.

I know there's some questions about the barriers paper, but still go back and validate, right, whether or not we're working on the right things

solving that.

And I bring that up for actually as a solution for a different problem that I had. At one of the MDIC meetings sometime this year someone was giving a presentation and they talked about self-driving cars. And whether you like or don't like self-driving cars they're point was as soon as a self-driving car has an auto accident that's big news. Never mind how many drunk drivers there are every weekend, right, barely gets covered, but one auto accident in a self-driving car and it's news everywhere.

So I wonder if we have a similar -- something similar that we should be concerned about. As soon as there's a patient-adverse event, something bad happens with someone who is on a device that's been through this process are critics going to say, no, this is bad, this isn't worth anything, their -- something bad happened to a patient?

I think by having the quality data saying, well, actually if you take a look the companies that have participated in this have lower complaints,

higher customer satisfaction, lower MDRs, lower et cetera, and show that the quality has been improved. Things happen, okay. Our patients are sick. I'm sorry that sometimes things happen.

But we have all this other data that says we have moved the needle, we have made industry better. And I think having that would help deflect some of the criticisms when -- when that bad thing happens.

MS. KEITH: Is there any questions from the audience for this section? Come on. You had questions earlier. I know you have questions.

MALE SPEAKER: Hi. I think this one is probably for Kimberly. I'm concerned about the dearth -- possible dearth of lead assessors. I think you said earlier there were 280 worldwide. And if everybody gets on board with this program will there be enough to go around?

MS. KAPLAN: So 380 was the number, but that was close. The number of lead appraisers that we continue to train every year grows. And I think if this program really hits it off and we are coming on that kind of capacity need that that industry within

the CMMI will grow, as well, as we create the need.

MR. ZACK: There was also over 2,000 appraisals executed last year across all industries. So there certainly is doing 30 is a pretty small number in 2018. And we're actively having conversations about how to scale both the pool of appraisers for the effort in 2018 and beyond.

MALE SPEAKER: Actually my question was similar follow up to that. With the new medical device regulation and diagnostic regulations coming up in Europe and the new burden put on the notified bodies how is that going to affect your ability to get quality assessors to do the assessments?

MR. ZACK: So I think if I understand your question you're asking are we competing for the same -- people in the same space?

MALE SPEAKER: Yes.

MR. ZACK: Potentially, but that -- I don't think that's been demonstrated yet so.

MALE SPEAKER: I actually had a follow-up question. I'm glad you guys brought up the small business thing because, I mean, that's where we live

with small businesses.

I brought this up that I was coming to the panel to a couple of the quality and regulatory folks for the companies we work with and describing kind of what CMMI is and what's going on.

And their comment was, "Oh, CMMI is the notified body for FDA now for our quality system."

And I was like, "No, no. I don't think that's right."

So one my -- the question about that is how do you avoid that stigma from a kind of a sales standpoint for that?

MR. ZACK: I think, you know, one of the things we've clearly heard today is there needs to be some -- we've identified some FAQ already. And those -- that was one of our working groups there was a communications working group.

And based upon feedback in sessions like this a set of FAQ was defined that went back to our steering team and that was further refined. And we actually ended up with kind of a front page and a secondary page of FAQ.

Clearly where we're at now is we're hearing from folks like Pat that we need the marketing slick and the next chapter of the FAQ which even gets down into the dirty details of specifics of the CMMI practices, some aspects of the operational playbook, the appraisal playbook.

But no good deed is unpunished with FAQ. It's there's always another frequently asked question and that certainly is one of them that the CMMI Institute is not your notified body.

MR. VINCENTY: So and I appreciate that question. First time I've heard it so we'll have to get back to you on how do we avoid that one.

MALE SPEAKER: It's a freq- -- it's a frequently asked.

MR. VINCENTY: It's a frequently asked question.

MS. CHARLTON: I just -- this is Sandy Charlton, Medtronic. I just want to echo and endorse Pat what you said about not if, but when that first, you know, adverse event happens for one of these companies that have been through the process, and it

will happen, that we are fully prepared and that we get there.

Because one of the fears we have as industry, and I so appreciated today, but we have that we won't have the gravitas and the movement and the progress forward enough in place before people change or maybe the mood changes and so we won't be able to do that and have the person in place that will then go testify that say, no, we've got the data. This makes sense and here it is.

So I just want to make sure that everybody hears that and that we do that work so that we're prepared when that day comes.

MR. CROUSE: I'd just like to add to that comment that, you know, clearly Robin and her team have already seen that as something that's going to happen and they're already aware. And, you know, certainly the intent of this is if the trust is there between industry and the FDA that it doesn't get played up that way.

But as we all know, media will do what media will do so we just all have to come to terms with

that.

MALE SPEAKER: So I have a comment and an anecdote that's kind of on that theme. In a previous life in a non-regulated industry or at least not as regulated I had a supplier that was CMMI Level 5 certified and they had no clue what they were doing.

What they delivered was absolute junk. I don't know how they got their certification. I'm not accusing anybody here, but I think my concern here is if there is room for the system to be gamed then you'll have an event like Pat was talking about where everybody says how did these guys get past the system; therefore, ergo, the system is not good.

MS. KEITH: I'd like to -- so go ahead.

MR. ZACK: No, no. You can --

MS. KEITH: I was going to thank you for being on the panel, but go ahead, yes.

MR. ZACK: I have definitely seen cases where organizations have approached CMMI with the intent to game it, as you've described it. You specifically mentioned a maturity level and you haven't heard Kim or myself talk in our presentation

materials today about maturity levels. And that's with good reason.

It -- there is an approach the CMMI framework which has maturities 1, 2, 3, 4, and 5. We're not leveraging that here because we recognized early our working groups, not just the institute, but our working groups and industry players in those working groups recognized if we said CMMI Level 3, this audience and your peers outside the room in the medical device industry would be like that's what I need to do. Get me the checklist to get to CMMI Level 3. Essentially we'd be setting up a prescription to game the system.

And we're not -- so there's a whole conversation occurring within the institute about those maturity levels and how to avoid those particular behaviors and how -- and discussion amongst the lead appraiser community about that.

But more to the point of this particular program the practice areas were selected by the working groups with the focus on a continuous improvement model as opposed to saying, hey, let's

just get to a score, let's just get to a maturity rating by design to avoid that gaming of the system.

I recognize that's not perfect. There will still be some folks that'll say, hey, I will look to game the system. I'm going to just, you know, put forth the least amount of evidence that I can or coach people up to say the right things.

But I think if we are really driving the culture of quality that we've been discussing here throughout the day within the organizations, between the organizations and the agency, we have an opportunity to move quality throughout the entire sector up higher and to avoid those scenarios.

MS. KAPLAN: All right. Just to emphasize what George said. There are two major groups of people that we see utilizing the CMMI framework; those who are looking at it for the maturity level and the group that's looking at it for continuous improvement.

And so we wanted to make sure that we utilize the model in such a way that it followed the latter format.

MR. VINCENTY: So and just to add to that we

actually -- that was one of the very early risks that we identified and really had engagement around. We brought in and really learned from manufacturers thanks to some connections through CMMI that had applied the model successfully and had applied the model unsuccessfully and what they went through.

And that's where we learned we're not driving towards that score. We're driving towards the mindset let's figure out to establish that principle first.

But in addition to that that's also why we're looking at what are some objective metrics that we can also look at alongside that, right. The push also with the shift in some of work to the more data structured elements that we get in enough data across enough companies you start to see which ones are gaming and which ones are not. And that's kind of what we're looking to establish now.

The metric might not be perfect, but it's a start and we can always clean it up from there. I think the key here is to start moving in that direction so that we're not just reliant on the

appraisal and what's going on there.

We've got another way to make sure that that's happening. We're trying as much as possible with the process to make sure that the intent of the appraisal is not there to drive the gaming, but we know that that's not going to be enough. We want to actually augment that in another way.

MS. KEITH: All right. Thank you, everybody, for participating in the panel. I believe you're on a break. 10 minutes, 15 minutes? 10 minutes.

(A brief recess was taken.)

MR. VINCENTY: -- announcing it for the last year. So he's a VP of quality at Innovise and he's going to share some of his experiences not just maybe with the model and the journey, but, you know, maybe some of the work that we've done up until now.

So Mark?

MR. RUTKIEWICZ: Thanks, Cisco. Yeah. I've been with the maturity model team for about three years now working with the group up front and then involved with the initial pilot. So let me discuss

some of my -- some of the Innovise experience on this process.

So where Innovise is a contract manufacturer in the Twin Cities I've been focusing on medical device for the last ten years. Our quality in 2013, the quality system was really designed with certified ISO 9000 13485, the standards, and ISO 21 -- I mean, 21 CFR A20.

The procedures there they were written to meet the requirements. Like a typical medical device company the procedures are written very focused on the requirements. And one of the things I wanted to talk about today is how you look at requirements and how that's going to tie out with how do you use a maturity model.

So we actually started our transformation before this. I mean, that's why I got involved with the maturity model because we were -- in 2014 we started a conversion of our quality system to a processed-based business system architecture. So instead of just saying these requirements are tied to these procedures we architected around 20 key business

processes throughout the company.

And then also as part of the process we defined the business process interactions as required per the ISO standards. The ISO standards talk about interaction, but to a level that's more defined on inputs and outputs of specific data types.

As part of that we kept building the system out. We actually as part we were involved in the proof of concept in June of 2016. So the assessors came in, they looked at what we were doing. And during that time frame they gave us a lot of good inputs.

One of the areas that we needed a lot of help on was in configuration management. And we knew that was an issue up front. Our product change control was a little more different because we were a contract manufacturer.

We were in the process of implementing a new ERP system at the time to put in more controls for configuration management. It just happened that we went live in between June and October of 2016.

So October of 2016 we ended up doing the

CMMI pilot with two other companies. So we actually could see changes in the way the CMMI assessment was -- our values on configuration management improved significantly with the implementation of the ERP system.

And then this year we've enrolled also in the voluntary program pilot. So we can just look at -- look at the history of how our systems have been changing using this transformation that actually started before the quality -- the maturity model assessment started.

So most medical device companies we've been talking here, you know, the FDA's really looking at it from the quality system regulations and how that's going to affect the audits.

But in a medical device company we have a lot more areas of requirements than just the FDA. So the ISO standards and guidance documents from those. Actually with the FDA it's not just 21 CFR A20, but you have 803, 806, labeling requirements.

All those requirements also have to be integrated into your quality system along with the EU,

the new MDRs, those directives and the Med Devs that are associated with it are the requirements on all medical device companies along with all the other international regulating bodies.

So how does a company manage all these requirements? Well, that's actually one of the key areas that is part of the maturity model. One of the key assessment areas is requirements management. And requirements management is not just your product requirements. It's these requirements that drive your business. So that's all -- you have to understand what those are.

So what we did at Innovise is we mapped our business processes -- business requirements to our business process. It's not a one to one so there are requirements for design controls, there are requirements for calibration and regulations, there are requirements for (indiscernible) material inspection testing.

But they don't really map to a business process one to one. They're multiples. You don't have a business process of design control. You have a

business process of product development. You don't have a business process of purchasing. You have a business process of material acquisition. You're trying to acquire the materials and that requires a variety of things in how you manage inspection and purchasing and other things.

So when we looked at that at Innovise when we did our process architecture we changed that view. And so as I was talking with the maturity model team how do I take that business process view into the maturity model and how do I tie that back into what we see every day with dealing with FDA trying to make sure that they audit us to requirements.

So the quality system is really two aspects. It's compliance and improvement. So you start with requirements and you become -- you figure out which requirements tie to which of your business processes.

But what the maturity model does is to say my practice areas are really looking at your process that you have. It's going to look at how well your processes perform across a variety of areas that they'll be looking at.

I mean, they're going to look at planning requirements, configuration management, training on every business process is really the way to look at it. So that makes an improvement of each of your processes.

So one of the things I've done -- looked at -- take this model is a different view of quality and improvement is to -- I created a matrix of quality on the bottom is compliance to requirements. And there's really fi- -- I'm using -- took some liberties here, but there's five levels of compliance requirements.

And then on the vertical scale is quality continuous improvement which is interesting what we're going to have with the CMMI Levels 1 through 5. And you don't want to be -- what we've always looked at is from a compliance point of view along the horizontal what we want to make sure we're complaint, we're Level 3 there.

But the question is the maturity model wants to take us -- we need to take us up the scale so it's really a two dimensional way of where you're at in your company. Are you compliant and what maturity

level are you at?

So one of the things I've done is look at it from a point of view -- you really want to start if you're down in the lower left you want to get to the upper right. You don't want to -- you don't want to just go straight on the horizontal. You're compliant, but then you're wasting a lot of money because you're in wasteful compliance.

Continuous improvement you want to move up the chain. But if you just move up the continuous improvement chain you're higher maturity level and you don't really understand your requirements you could still be out of compliance.

So the CMMI model actually takes you up that chain because it -- you have to understand your requirements as part of the maturity assessments. That's one of the core foundational configuration management, requirements management, project planning, those are some of the areas that are assessed in the -- in what we're looking at for the initial assessments here this year.

So the CMMI assessments are used -- using

the CMMI model's general and level specific practice areas. So each of those areas that I talked about practice areas that, you know, George and Kim have talked about.

CMMI does not assess to the FDA regulations because it's really not about the reg- -- it's how you implement them. Doesn't ensure compliance to all the requirements. That's the company's job because it's not just FDA they're looking at.

Because if you're doing your business you're not going to write a quality system that's just FDA and then you have another one for Europe. You do -- everything is in one process.

So what we need to do as part of this we need to map practice areas to medical device company business processes. Not just the regulatory requirements because the requirements are different for every company.

So in order to maximize the value -- and this is what I've done at Innovise. For maximize the values CMMI for each company you define what your business requirements are. And a lot of times that's

right in your quality manual for your scope what regulations that you follow.

Defining what your business process and define your interactions between those processes. Then your -- the assessments -- CMMI assessments will be done against the business processes that you have. It makes it easier to really make changes.

And as your processes mature CMMI will review the more -- will review more and more practice areas as the higher levels you go.

And finally the expectations for the next assessments which it's going to happen -- and we talked about -- a lot of people talked about that. The assessors will talk to people doing the work. There's no front room or back room required because you really want to get -- understand what's really happening.

They'll find new ideas to improve, not just comply with regulations. It's an ongoing journey. You're never there. Even if you reach Level 5 you're never really done.

And that's what, you know, I've learned with

being on the team for the last three years and I think our journeys going to be very successful. Thank you.

MR. VINCENTY: Just out of curiosity if there's any questions for Mark or no?

So next I'd like to bring up is it Gene Parunak? Close. I'll get better. In2being, right. So I'll let him take over and…

MR. PARUNAK: Awesome. Thank you, Cisco. And thanks, everybody, for sticking around. Like many of you, not all of you, we didn't have a real good idea of what CMMI was all about before we came here. And so, Jennifer, thank you for receiving our slides on a federal holiday that were made beforehand. So we'll see if the slides line up with what we talked about today. Hopefully they do.

The one thing we did know going in is that there really is a new FDA. We have been very impressed by our interactions with the agency. Robin, you and Jeff were in San Jose just a few weeks ago. Your CDRH town halls are wonderful assets. The engagement sometimes bowls you over so we're really thankful for that.

I want to talk to you just a little bit we're talking about maturity today. I want to talk to you just a little bit about the infants of quality and regulatory maturity which is startups. And I'm not just talking small business. I'm talking pre-clearance startups. This is the first product and we haven't even gotten our regulatory clearance yet.

These aren't the focus of the pilot program as I think we learned today, but someday they may be. And they're certainly going to learn about it, they're going to hear about it. What do you want them to take away? What impressions do you want to give them for the larger companies that may be in the room? These will someday be your M and A targets so we definitely want to get them in the pipeline, as well.

In our business we're focused on medical and life science product development which for us means a lot of prototyping of really stage ideas, program management consulting, and increasingly educational intensive offerings for startups because of the need.

We don't believe you can get there by throwing developers, regulatory folks, and quality

folks in the same room and saying go. At the early stage we believe you need regulatory and quality conversant developers to move ideas forward, okay. Later stage you can do that. Early stage you can't.

We've been in business for seven years, 42 employee years of startup experiences. Our audience is doctors, entrepreneurs, small to mid-size companies, and VCs and we're intent on demystifying the regulated development process because there's too much mystique. So when we what the FDA's doing these days we just -- we just eat it up.

Now startups don't know where to start. They'll hear you need a QMS, you need to go through a 510K. And they'll go out and they'll drop literally tens of thousands of dollars. These are very small startups. They'll drop tens of thousands of dollars on a drop-in-place QMS or a very, very opaque regulatory classification.

Oh, you're the expert. You told us what it was so now we just trust it and we go. And often times folks will educate the startup and say this is how it interplays if you make this change to your

claims, if you make this change to your intended use here's how it's going to affect your classification.

Here's what a QMS is supposed to do. Here are the parts that apply to you today. Here are the parts that are going to apply to you tomorrow. So one of the ways we try to help with that is explain the classification analysis, point them to a 513G, do a lean stage appropriate QMS growth.

You don't need it all on day one. You certainly do need some of it. Let's figure out where those fit. So that's how we're trying to push against the culture question that's been brought up today.

We did our CMMI homework a little bit. We did the -- I hope it pays for the part of the plane ticket. We did the service and the product development or we've started through it. We're about 50 questions in. And we've started to get a sense I hope if this is representative, Kim, of some of the approach that CMMI takes so that was very helpful for us to see.

And I think what we came away thinking was it is a language appropriate for folks who are versed

in quality. Whether it is for startup folks or not, that's another question.

In fact, I'm going to jump to my third point here that was a little bit out of order now that we've heard today's presentations. I want to ask you how early stage investors view this program.

I actually think they might like it more than you realize. They might like it because it gives them a way to benchmark against other things in the industry. The problem is today it will probably give them a completely false and irrelevant benchmark. It's not focused on the early stage stuff right now. It's beyond us, right?

So questions that follow is stage consciousness a part of the baselining that we heard about today may be something to think about. For those early stage folks who really need design and development and document control and things like that can you bring your baselining down to their level and say for a company at your stage you're doing a pretty good job? You're not mature like you need to be when you're in production, but for your stage you're

mature. Just a thought.

How should we view it in light of the already existing QSR and ISO 13485? I think we've been talking about that today. And will it be truly voluntary as time passes? As more and more people come to it as it's seen as a good thing will it be voluntary, will there be bottlenecks with the provider?

Just to get your minds going at whatever it is, 3:30 on a Tuesday afternoon, I wanted to give you an example. I just switched one letter out so it's obviously applicable, right?

And FAA example. I enjoy flying Ultralight aircraft, rag wings we call them. You know, you ever seen the things with the little rag wing over the head and the big backpack on your back?

Well, my wife and I have eight children and I want to be able to take my kids up with me. I can't do that if there's a single seat in it so I have to go up to the next level in the FAA's hierarchy which is now something called sport pilot, okay.

I don't know if any of you are pilots or

you've seen what's happened with sports pilot, but it used to be largely unregulated and now it's a public/private partnership sort of system. It has killed this type of aviation. It's been very, very damaging and I think you'll get consensus on that.

I'm not saying every analogy you make here is exactly right. Just an example you may be interested in looking into as you look at how these public/private partnerships can work well or can work poorly.

What it's done is to really load a weight down on these folks. I'll just give you one example. I called up asking the one approved provider in the U.S., commercial provider, FAA approved provider, and I said, "How can I get this maintenance rating for this type of craft?"

And they said, "Well, we're thinking about running another class in Pennsylvania" -- we're in Michigan -- "next spring. We're not sure if it's happening. We'll put on the wait list."

Now if I'm a recreational pilot I can wait, but if I'm a small business with limited funding,

limited runway and we're talking med devices, that's the end right there. So just a warning. Something to think about different industries, different regulatory organizations.

To sum up, kudos. The FDA really is the new FDA. We are very impressed with what we're seeing from our little niche there in Michigan. We sense it there.

Startup comprehension of what's required has not caught up. Tools that increase stage appropriate education and benchmarking are welcomed. We would -- we'll pass them on and preach the message.

Programs that are really compelling when you first hear about them but increase the opacity and the bottlenecks, not so much. And that's obviously what we'd like to see less of.

So thank you for the opportunity to speak and contribute. Thank you for today. We really appreciate everyone and for having us here.

MR. VINCENTY: Thank you for that, Gene. And we'll be talking because this is a space we want to get into and figure out what the right approach

would be.

Next I'd like to call up Jack Mitchell. He's -- I know I saw him earlier.

MR. MITCHELL: Good afternoon. I'm Jack Mitchell. I'm director of health research for the National Center for Health Research.

We produce unbiased health research to inform public policy and we advocate for patients and consumers. NCHR accepts no funding from medical device or pharmaceutical companies so I have no conflicts to report.

CRH is to be commended today for continuing to follow up on its non-strategic goal of improving medical device quality and for outlining innovative and collaborative programs under discussion today.

Patients can certainly benefit from increased device manufacturing quality and data transparency. Industry deserves a reduced regulatory burden and reduced costs if the criteria outlined can be successfully met and carried out in a uniformed fashion as we go forward.

As a research organization examining

scientific and medical evidence to prove the safety and effectiveness of medical treatments we remain concerned about the 510K substantial equivalent systems to frequent reliance on opacity of clinical data for premarket approvals.

On the -- while the efforts presented today may eventually shift that paradigm somewhat, it would seem that industry and FDA believe generally that post-market surveillance will be sufficient for protecting the medical needs of patients and consumers.

But what about the quality of medical products when they are first on the market and for the next few succeeding years?

A recent HHS Office of Inspector General report noted that the recall of medical devices almost doubled from the period 2003 to 2012. In a six-year period, for example, more than 200 types of cardiac devices were recall according to the report.

Additionally, a continuing failure to adequately track just seven makes of cardiac implants cost Medicare more than $5 billion. The inspector

general was able to only estimate expenses that are the tip of the iceberg.

For example, replacement surgeries for devices that are under warranty, but not the actual cost of all Medicare services for all the cardiac implants that had to be removed. Device failures not only waste huge sums of taxpayer's money, but obviously expose patients to risks from additional surgeries potentially causing irreparable harm.

Now I mentioned this angle of device recalls for a reason more relevant to our purposes today. If the increased number of recalls reflects better post-market surveillance then that's a positive trend.

But regardless of the reason for the increase of the recalls in recent years these recalls speak at least to a degree of a failure of premarket regulations. Therefore recalls demonstrate the critical need for improved medical device quality and for more clinical testing of such devices before they are put onto the marketplace as well as improved inspections of manufacturing facilities prior to them going on the marketplace.

As a positive sign I would note today that your pilot program addresses at least some of the inspectional issues at hand with some new approaches. And hopefully that will be helpful to both industry and the agency, itself.

The agency is coming under increased pressure through user fee agreements in the 21st Century Cures Act to approve medical devices more quickly. At the same time the largely passive FDA post market surveillance system is not able to keep pace.

These trends will place more urgency on maintaining high and consistent manufacturing and quality standards for medical devices. We're happy to hear from CDRH compliance today that positive patient outcomes are a very high priority for this pilot program.

And we appreciate that the speakers today have emphasized patient input. I hope that also that the patient engagement meetings later this week will further focus CDRH on patient issues.

Nevertheless, the center's laudable efforts

to work with industry and improve and standardize these quality measures and increase transparency must be seen in a larger context of increasing pressure to ease regulations, speed approvals, along with CDRH's lack of resources and funding to make post-market surveillance more proactive and effective and towards the critical goal of improving patient outcomes and safety.

Thank you very much for allowing us to express our views.

MR. VINCENTY: Thank you, Gene, for that perspective. Next I'd like to call up Adrian, Adrian Furey. He's going to share some of his story at Zimmer.

MR. FUREY: Good afternoon, everyone. My name is Adrian Furey. I'm the senior vice president of global operations and logistics. And I just want to give you a flavor of some of the work we're carrying on at Zimmer Biomed which really reflects what we talked about earlier this morning.

And up to this morning this is what I called the maturity model and now I'm going to have to rename

that. But basically this is how we're transforming our sites.

We have 38 plants globally. And the way the model is built is facilities go through different levels of maturity themselves. Phase one is all about eliminating unplanned events, doing routine things routinely whether that's maintenance, quality excellence, engineering, it's all the same.

And as you go through the levels of the maturity model the plants get more complicated. And as we went through the journey this morning it's clear that we have some plants that are in the Phase 3 section and I'll talk to MES later.

But we have plants there and we have plants in Level 1 and Level 2 and it's huge diversity across our 38 locations. And we're trying to use this model to unify everybody and drive the quality excellence -- quality excellence journey.

So in terms of one real differentiator in our business has been doing a three-year strategic plan for every one of our sites. And out of that process came our MES and journey.

Now when we started MES and manufacturing system we didn't really have a whole lot of knowledge about what we're doing. It was very much a pilot kind of a little bit like this morning's conversation. Very exploratory, where could it possibly take the business.

We knew paperwork was not the future for medical device manufacturers. And when we started in our plant in China and Ireland our typical route or our history could be over 80 pages long with 4 to 500 data entry points.

And today in our plant if you asked a new team member on the shop floor to explain what a router was they wouldn't actually know because they've never seen one. And it's been a hugely transformation journey across all aspects of our business.

You say qualities good for business. All our metrics went absolutely the right way and efficiency, cost, quality excellence, lead time, everything you could measure the plant by and utterly transformational and something we're going to take to our other facilities.

In terms of just a little bit of what MES is -- and I actually had this conversation with an FDA investigator last week. So deploying MES is kind of like the umbrella software. All the tools by which you want to run a controlled plant touch off MES.

So if an operator is using a gauge to check a component on the shop floor and that gauge hasn't been calibrated the system won't allow them to use the gauge. So you can imagine quality holds are hugely disruptive to our business basically don't happen in plants we've deployed MES.

In fact, one team member on the shop floor in one of our plants actually commented it was one the best things we ever installed. And the reason I'm delighted with it is because instead of having eight leaders trying to run the plant I now have 4 or 500 team members actually running the plant.

They're coming up with better ways of doing things, faster ways of doing things, eliminating waste, and driving all our quality metrics in the right direction. And it's been hugely transformational.

And coming along with that then is the culture piece. It really enforces compliance at source and we have one set of numbers, one set of data for our plants. And recently I sent a mail to one of the plants an MES and I said, you know, how long does it take roughly to process an NCR and for one of our product lines it's like 9.2 hours.

In a similar plant not MES it's like 50, 60 days. And it's just that agility that you lose in the business. And that's why I think those plants are ideal for the -- for the innovative presentation we had this morning in terms of quality excellence and getting assessments done on those facilities.

We have three plants deployed in Ireland. I have two in Ireland and one in the U.S. in New Jersey. And with MES it's been utterly transformational in them all. And we are looking to bring it to our corporate headquarters in Indiana in the first half of next year. And they're a stepping stone to our two facilities in China. And we expect similar performance results from each site.

And to give you an idea of some of the

metrics, as I said, it's not all -- it is quality and it's everything else -- everything else with it. It eliminates waste in every single way. And I honestly couldn't say there's a bigger culture transformation than what we actually did with the MES system from a manufacturing point of view.

And finally it's also -- it's also strategic for our business. Yesterday I chatted with one of the guys and it's almost something unthinkable we wouldn't have done four or five years ago where they actually spent a day with Dell. And because they believed that the data and the analytics we're getting from the system we're using about maybe 20 percent hours.

So they spent a full day in a Dell plant looking at the data and how can we possibly use that data to drive even better results and a higher level of quality performance in our business.

So when we launch this we obviously have the core implementation and very little customization. It's very much an operations-led project. Like operations have to own quality, they have to own the systems and then IT facilitators and the deployments.

In terms of the standardization it really drove the elimination of what you might call a shadow factory. So even though on day shift certain things might happen a certain way in a procedure and on night shift maybe it doesn't happen exactly the same way.

Basically you find all that out through your MES deployment before you deploy it so that worked really well. As I said, it's really allowed 4 or 500 people in the plant to drive continuous improvement. It isn't coming from me or it isn't coming from engineering. It's the team members on the floor who are the real experts. It's giving them a voice and they're able to drive the agenda. And they drive actually the workload for a lot of our QEs and our MEs.

It's enabling advanced manufacturing. So actually advanced manufacturing is a term you hear more about in our industry 4.0 if you're in Europe and we actually have our first assessment on this particular category in November in the two plants that have MES deployed two or three years ago.

So kind of like the quality initiative

today, we're looking for that to really show us strategically what should we be doing with manufacturing three, five, seven years from now. And we wouldn't have been able to do that.

And then obviously knowledge sharing, design for manufacturing, supplier quality, and predictive analytics this is all in the future and this is -- this is what we want to try an engage and really have the manufacturing guys plugged into -- plugged into these areas as we drive quality excellence throughout our plants.

So I'd just like to thank you for time today, Cisco. I really enjoyed this morning. And there's the next guest. Thank you.

MR. VINCENTY: So I want to thank everyone for attending. This is our open period so last chance any comments, any additional thoughts? Got one more.

Oh, okay. So I'd like to introduce Joan Estre Richards?

MS. RICHARDS: Hello, everyone. My name is Joan Estre Richards (phonetic). I am actually a compliance officer for a medical device packaging

company.

As you know there's a big difference of understanding quality management systems from a bigger company's point of view to a very small company. And, in fact, a lot of the small companies are very intimated with that term quality management systems.

And I just happened to have -- be part of a team that have an understanding about it, but it's a matter of like as mentioned earlier this morning it's improvement, it's a constant improvement and being consistent and being able to adapt into not just the industry, but apply it to not just the paperwork but in practice at the same time.

There's a lot of companies also that have not a lot of understanding of how the FDA works. And I think -- I'm not sure. It wasn't mentioned earlier, but DICE, FDA actually have a division that has helped me understand more and be able to ask information on how and what other things I need to do as a company or as an officer -- as a compliance officer in order to help the company better.

The FDA is not an enemy company. In fact,

they are actually continuously developing programs and divisions in order to reach out specific -- I think more they collaborate on bigger companies on information, but they reach out to small businesses on how they can improve their implementation.

So I would really encourage everybody there's on the website of FDA if you'll look at DICE it gives you the information of who to reach out to. It's been helpful for me and it's basically it's a free communication with the government agency.

They can be really intimidating especially if you don't have understanding of what you have to do first or whether or not have you have to do a 510K or do a registration. You should either do a listing first.

I have a fairly good understanding that you can't have your registration or listing without a 510K if your product is categorized as a 510K. So having the system that was presented today it's not a shortcut for you to not have a 510K. I just wanted to clarify that.

It's actually helping you to be a little bit

more organized in order to have a successful 510K in the future. That's one of the info- -- an example I think that I could see -- like I could see this is going.

I don't really have anything else to add, but I hope that information is helpful for everyone. Thank you.

MR. VINCENTY: With that I'd like to bring back up Robin Newman hopefully to close us out, take us home, let us out early, go to happy hour.

MS. NEWMAN: Well, I want to thank everyone who's managed to stay with us through the whole day and those of you that had to early, as well, for joining us and having a -- letting us have this opportunity to share with you our vision for what we're doing in the future and then for sharing your thoughts and ideas.

So today you've heard the FDA outline what we think is going to be a very exciting and very interesting new way of working through this pilot process. We've had a chance to hear from industry and our colleagues and hear some of the success stories

and also, frankly, hear some people's concerns.

And I think that those are very valid pieces of information for us and it's important for us to bear that in mind as we move forward.

I'd like just kind of leave you with a couple of thoughts and this has to do with -- now tiny, small company, big company, whatever. If you have a really simple product, you do not need a sophisticated solution. If you have a sophisticated product you can't afford not to have a sophisticated solution.

The other thing I want you to bear in mind is that, as I said earlier, all the things we're doing here at the agency are really coming together to better represent the needs of the patient.

So not only is it Case for Quality, but look at some of the other things we've done in the past year and a half or two. The benefit risk guidance document both premarket and post-market that have come out, putting patient benefit before risk and the analysis around that, the general wellness guidance document that's come out where -- because some things

really are not medical devices and I really don't want to spend any time working on those things.

So we're looking -- there are a number of things like this all of them leading basically to the same place and that is a highly patient centric, quality focused, beyond compliant perspective from the side of the agency.

So, again, thank you very much for coming. Thank you for sharing. And please don't hesitate to get your comments in if you have additional comments that you'd like to make to us. We look forward to hearing that and getting your feedback because we'd like to make this 2018 pilot an extremely successful one.

So have a great afternoon. Thanks.

(Recording concluded.)

CERTIFICATE OF NOTARY PUBLIC

I, MICHAEL FARKAS, 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.

MICHAEL FARKAS
Notary Public in and for the
State of Maryland

CERTIFICATE OF TRANSCRIPTION

I, LISA BEAUCHAMP, 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.

Lisa Beauchamp

October 19, 2017 _____

DATE LISA BEAUCHAMP