U.S. FOOD AND DRUG ADMINISTRATION

FOSTERING DIGITAL HEALTH INNOVATION: DEVELOPING THE SOFTWARE PRECERTIFICATION PROGRAM

PUBLIC WORKSHOP

Day 2

Wednesday, January 31, 2018

8:40 a.m.

National Institutes of Health (NIH) Campus

9000 Rockville Pike

Ruth L. Kirschstein Auditorium

Natcher Conference Center, Bldg. 45

Bethesda, MD 20892

Reported by: Casey Smith

A P P E A R A N C E S

BAKUL PATEL, Associate Center Director
Center for Devices and Radiological Health
MARISA CRUZ, Senior Medical Officer
Office of the Center Director
DAVID RITSCHER, Senior Consultant
Cambridge Consultants
SETH CARMODY, Ph.D., Cybersecurity Program Manager
Office of the Center Director
MORGAN REED, Executive Director
ACT | The App Association
TONY FARANESH, Research Scientist
FitBit
ESTHER BLEICHER, Senior Policy Advisor
Office of the Center Director
DAVID AMOR, Quality & Regulatory Expert
Pear Therapeutics
FRANCISCO (CISCO) VICENTY, Program Manager
Office of the Surveillance & Biometrics
IAN MCFARLAND, CTO and General Manager
Pear Therapeutics

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

BERNHARD KAPPE, Founder & President
Orthogonal
DANNY BERNSTEIN, CEO & Founder
metaMe Health
HOWARD LOOK, CEO & Founder
Tidepool
MATTHEW KERR, Executive Recruiter
Abbott
ELISABETH GEORGE, VP of Global Government Affairs, Standards & Regulations
Philips Healthcare
MEGAN CODER, Executive Director
Digital Therapeutics Alliance
ROXANE MODARES, Consumer Safety Officer
FDA
JOHN MURRAY, Software Compliance Expert
Office of Compliance
LAILA GURNEY, Head of Global Regulatory Affairs
GE Healthcare

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

PATRICIA SHRADER, Senior Counsel
Hogan Lovells
ROB MCCRAY, President & CEO
Wireless-Life Sciences Alliance
KEITH REID, Group CFO
KJR Limited
SAMANTHA GOTTLIEB, Ph.D., Medical Anthropologist
University of California, Center for Science, Technology, Medicine & Society
CHANTAL MCMAHON, Ph.D., Team Lead
Medtronic Diabetes
SYLVIA TRUJILLO, Senior Counsel
American Medical Association
JOHN BURCH
Angel Capital Association
JILL DEGRAFF, Partner, Healthcare Division
Manatt Phelps & Phillips, LLP
NANCY MYERS, President
Catalyst Healthcare Consulting

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

JAKE NARDONE, Senior Regulatory Affairs Specialist
Dexcom
MICHELLE JUMP, Principal Regulatory Affairs Specialist
Stryker
GORDON KESSLER, General Counsel, Chief Administrative Officer
AiCure
AGATA ANTHONY, Regulatory Affairs Executive
GE Healthcare
BOB ROGERS
BETH STEPHEN, Senior Regulatory Affairs Manager
Medtronic Diabetes
BRANDON ARBITER, Vice President, Product & Business Development
Tidepool
SUSIE O'CONNOR
Boston Scientific

P R O C E E D I N G S

MR. PATEL: All right. So I guess as people are settling in, thank you for yesterday. Thank you for a great participation yesterday and thank you for being engaged and still coming back for punishment again. This has been a great experience for me and I think -- I've talked to many people here from FDA and from other organizations and everybody seemed to have a phenomenal experience and sort of the openness, that sort of came up. I was telling somebody earlier, this felt like our site visits. Day one was all about setting the stage, understanding what people are confused about and answering questions and raising sort of things that people care about and, you know, assumptions about the program, some myths about the program and so on. And day two was like, let's get in and try to roll up our sleeves and solve what we're trying to solve for. So, I feel we are there. But I want to take a few minutes and make some observations and what I heard from folks walking up to me and I

heard people talk about and some -- reflection on some of the panels. So, give me a second as I look at my notes to talk to that. So -- I should probably use this piece of paper. So there are a few things we started off the day and we relayed the concept out and we said we are here in the program -- in the very first part of the program. So, the concept where we laid out, where we had the cloud picture -- I wish we could sort of bring that up again, but just imagine that in the background. And we said we're in the very beginning, understanding what an organization does in excellence. That does not necessarily mean we need to forget the rest of the ecosystem we're trying to build. We're still trying to figure out as part of being excellent in an organization what does that mean for understanding real world evidence. What does that mean to sort of be part of -- you know, using that real world information and data to be part -- to -- and leverage NEST and the governments around NEST to sort of inform, one, the regulatory structure and two, the

evidence creation that happens. That's one thing. We should not forget while we're thinking about today in our break-out sessions the part about not every product needs -- should go to market without review. There will be some products on the high risk -- will still need to be reviewed. The question we're having today in front of us and you'll see sort of understanding excellences, like how do you -- sort of, where is that line of what products to review and where do we think as the community is important for somebody else to review other than the evidence that's been created by the company itself. So think about that. Part two of the review part -- question we're going to solve, not -- maybe not today. But if you have ideas for any and all of that above, please don't hesitate to bring that up. Make sure that your moderators in your groups actually know where the parking lot poster is, the easel -- sticky pad that he can put those thoughts on there because they're all -- all going to be helpful for us because they're all input. And now that we have you as a captive

audience, we will get that input from you now rather than later. So do that, please do that because that's important for us. I want to emphasize that. So, don't just look for what -- what's happening today. Today is about diving deeper, but also as thoughts come up, put those thoughts up for us. I do want to -- I heard a bunch of assumptions and questions and concerns that sort of came up through all the panels. So, panel 1 and 2, you saw the experiences. I wanted you guys to have the same experiences -- experience of day one that the pilot participant had. I'm hoping that you had that. So, the rest of the panels, panels 3, 4 and 5 raise really interesting concepts and it's not something that we had taken very lightly. The concept of clinical evaluation is not taken very lightly. So, if folks are thinking that there's going to be no clinical evaluation for digital health and software, that's not true. The international community put out a document and we just recognize the final document, Form FDA, talking about when

Software as a Medical Device needs -- and what does it mean to be clinically evaluated. That was a concept that was very foreign for people in -- in the entire world and we have tried to clarify that. Now, we went from, you know, maybe 50,000 feet to like 20,000 feet, but we still need more work and we'll have to figure that as we go forward, like what's being provided where and what level of details are necessary and that's the work that needs to be done. But that's not the assumption, that we will have no clinical evaluation because like somebody said in the panel yesterday that investors will never pay for things that don't work. And here we are trying to set up a system leading forward in -- into an environment that we want these products to work. And we just want -- we want these products to be invested in, so it actually helps patients and helps the people we serve. So that's really the intent there. So, if folks are thinking about that I want to clear that up. And I touched upon no review versus review. So, there is going to be a review. But

it will -- it will be a different type of review, is what we're talking about. What should it look like and that's the question we're stepping back and saying, 'What should that review look like?' That independence -- and I think somebody else in the panel mentioned about self -evaluation, even from a excellence perspective. Self-evaluation's great, but there's always a place for independence of sort of having a second eye look at it and that's important as well. The third point that sort of stuck out for me was transparency. I cannot tell you -- one of the main tenets of this program is about transparency. Transparency at multiple levels. Transparency in terms of what we're thinking in terms of the certification of the -- of the organization, where they're fine, they're think -- even thinking -- and you'll see the third break-out today talk about dashboards. The concept of dashboards is about transparency. So, how is it posed and how does it sort of explain and how it's accessible for people, I think one of the models -- excellence models --

excellence model frameworks talked about -- you could go into their website and see who is -- who has what from a -- I believe it's Ballreich (ph) and it talked about who has borrowed what and at what level they got certified and what they're allowed to go to market for. That transparency is really what we are also thinking about putting it into our system. So as the program is built, there is some knowledge and there is some, you know, clarity in terms of when an organization is certified, what does that mean, what -- where does that get them and it creates -- creates a trust for everybody. And that's really what we're trying to get to, is trust in this organization, not just for us, but everybody else as well who are -- who are in this market place. The second part of transparency is about product transparency, like how do we get there and we don't have an answer for this yet by the way. What does that mean for a clinical performance of a product? Could we make it public? What kind of information we can make public, what kind of

things that we can share are -- people are willing to share about their products, their performance in the field? We haven't figured it out and that could be open for discussion, as like what does that look like. So, there is people, you know, reading a label and reading information about a product and the marketing way may not necessarily be the best, sort of, level of transparency, what about the performance of the product, what about actually what's happening real life with the products itself in terms of their clinical and technical performance? So, we are thinking about those things and I don't -- I'm not sure we have a great answer for that yet. But that's something that we would -- we would also want to explore. Another thing that came up was whether the system, we're thinking of evaluating our organization, is that static, once and -- you know, once and you're done? Actually, we're thinking the opposite. We're thinking towards more the continuous model. That's why if organizations on their own were to create some sort of metric that we can -- on a

continuous basis that we can just peak into and sort of get their transparent -- know of, like, how the health of the organization is, the better we would be. Now, when we get to a live feed of what the -- our excellence of the organization is, maybe that's very aspirational, but I think that's -- that would be an ideal situation. How do we get there, I don't know. We may have to walk before we run, but that's really where we're also thinking about, is like 'how do we think about this on a more continuous basis' so that we have an access to how good the organization is at any given point in time. So backing from that you can also think about what does that mean, how -- what system should be in place, should that be a person that goes into and write -- does an appraisal. I think the person and appraisal in the way that's been done today, I'm hoping that -- that becomes automated to some level, that doesn't necessarily require a person, but it's built in and ingrained into the -- into the organization itself. So, I'll give you an analogy. It may not be a perfect

analogy, but I'll say that -- if there was a black box or if there's a -- and that monitors the entire -- entire things that we want to think about excellence in an organization and it just does the algorithm behind it and sort of understands what the checks and balances are, needs to be -- and then presents something live to the CEO of the organization and that gives the same transparency to us, what would that look like? So, again very high-level concept, but that's one level down, we need to think about, like, what does that look -- that's the goal and that will be an ideal state. I'm not sure we'll get there soon, but we are trying to get there. So the most easy path towards recognizing and understanding where people are in the excellence journey is going to be the best adopted, sort of, program that we think that -- that will happen in the space. So, I want to talk about -- oh, the biggest thing I want to talk about, there was a lot question about small organization startups. I can tell you we spend lots of time talking about

that in our site visits. And I'll emphasize that one more time, that it's not about small or large how we're starting to think, we're starting to think, 'How can this program scale for small?' So it's not about leaving people out. It's about how do we start off design in the program that includes small and large. Now, that doesn't mean one model fits everything. That means that small companies may be looked in a different -- same principles, different lens to talk -- to look at -- recognizing what they're doing as a small organization because the resources may be different and how it sort of applies to the excellence principles might be sort of different from that perspective. But that's what we want to figure out, the -- from the get go, small and large, different variety of people or organizations should be -- is part of the program that we're trying to build. What does that mean in terms of recognition, that's for -- something that we need to figure out. And this is where I need your help on, so there are a bunch of people

in this audience thinking about small organizations, been in a small organization, thought about, you know, what it means to be in a small organization, from startups to two person organization to large organization, how do we sort of include that as part of the design and what if -- if you keep the excellence criteria of what we talked about, the same, recognition of what they're doing in their organization, how can that be sort of abstracted? So that's -- that's the task in front of us and I would say that -- that would be a challenge for all of us to start thinking about, what does that mean. We also said in the past -- in the very first model we put out, we said there may be multiple tiers of recognition. That's the journey discussion that happened at the scorecard -- the models panel that we had yesterday. The journey about -- somebody may not be there at the very highest level on day one, somebody may be there at the highest level, but what's the glide path for people to get there. We want to encourage people who want to be in the

space -- may not be necessarily software as a medical device today, but intending to be there. So, the concept here is how do we sort of make sure that enough -- enough expectations are set when they enter the field that they can start collecting, start improving and make that -- and being recognized for those right things that we expect people to be working in the space for? So that's the glide path we're trying to create, both from an evidence perspective, from maturity perspective as well as for recognition perspective. I don't have an answer, we put out -- put out a concept of -- well, two levels of tiers that we may recognizes. I don't know if the answer needs to be three or -- you know, I think some models talked about having bronze, gold -- bronze, silver and gold. It could be that possibility. But it has to be lined up with a risk of the products they're making because at the end of the day, we need to know and have trust in people, this organization that can produce those products that can go to market in a -- in a

reasonable way. Does that make sense everybody? Looking at my notes. There're a couple questions that came up on the fringe. I will talk about that. So I did hear about the discussion on metrics. So that -- and KPIs. There was lots of discussion on KPIs and metrics. I want to touch up on that a little bit. This concept of triangulation is really, really important to sort of think about. So, there's a lot of work being done on people saying that you can't just rely on one -- one metric to say that that's indicative of a great process in place, great organization that exists. I think as businesses, we all know that you need to look at more than one thing, multiple things to sort of see your -- you have confidence in the -- in the things that you actually have put in place to deliver products. So, what are those triangulation metrics and outcomes that you can sort of then -- that supports the outcomes of a great process that you have in place. The concept triangulation should not be lost on people. So, we should always think about, like how do we --

and you will see this discussion happening in break-out too, I believe, that talks about that. So, let's think about that. It's not about one metric equals success. It's about how do you show that in multiple ways to -- to show that you are actually -- you do have excellent process in place. So, just -- I wanted to raise that as one of the things and that's exactly why we have the -- the break-up session, talk about -- a bunch of people asked me about international regulators, how our international regulators thinking about this? And I can tell you the work we're starting off with is work that was done in the international front. You saw the work -- I talked about Software as a Medical Device. That was something that we started on the international front and we wanted to sort of take that, you know, 20,000 feet level consensus to the next level for US. And I -- I can tell I've got enough interest from the international community to -- and they're watching what we're doing in this space very actively. And there's a lot of

discussions about how they can be looking at -- I can -- I'll tell you the conversation I just had earlier. For this program to be successful we need to focus. For this program to be, you know, getting out of the gate with a minimum viable program by end of this year, we need to be extremely focused. This is why you find me talking all the time about 'let's focus on Software as a Medical Device.' Can it be applied elsewhere? Yes. Can it be applied in other parts of the world, yes. Can -- but if you start diluting our efforts in other areas, I think we will be -- will be stuck and not -- not necessarily make progress. So I'm very, very, you know, focused on trying to get this off the ground by end of the year. My leader would actually tell me to do it much sooner than that and he's smiling, but that's -- that's the point, right? So, I think the world is changing so fast in front of us. There is so much demand for something new to be in the space. I mean, the evidence that you guys are here, that tells me that, right? And

there's interest in the space. I want to tap into this interest that you already had -- that you already have in this program and the -- and the potential of this program to be successful and how do you sort of build that, so we truly can have something that can be stood up by end of the year and that's the goal. So, let's stay focused, is my call, let's stay -- sort of make sure that we all chime in input -- input into this -- into this area that we need help with. So really calling on you to engage. I think I covered most of it. Let me -- so, I can take a couple questions. I don't know -- I don't know if we have time. Marisa, do we have time to take questions or -- or observations? We didn't plan for it, I know. Marisa will kill me if I modify stuff. But I'm known to modify on the fly, so that's good. So, two things before -- I mean, so people have questions or want to sort of throw out other observations, please stand up, get to the mic and I would be happy to sort of, you know -- I think at least help people hear what you took away and

maybe we'll just spend a couple minutes to talk about that. But before we get started, let me just say one thing. I'd ask people to raise their hands if they belong to groups or they are part of a group that -- that is excited about this program and want to help. Can you -- those guys who raised their hands and willing to help, can you get to the registration and talk to Maggie Fu? She's collecting names of the organizations. So, we're asking people to say who you are, how do we get in touch with you, what kind of organization you belong to and what kind of perspective you bring to the table. And we want to sort of make sure that this is truly crowd source, from that perspective. So, how -- so please do that in one of the breaks or right after the session to sort of make sure that we have your information, that we can sort of then connect with you and figure out a way to sort of do this. And if you have ideas after the fact or if you sign up and say, 'Oh, we have idea, this is how you can engage with us,' I want to hear that so we can actually figure

out a way. One of the challenges we have today is we don't have a good mechanism or we haven't thought about a great mechanism to engage with everybody, we -- a little bit strapped on bandwidth and we want to make sure that we are using the people we have in our teams to sort of engage with you, give you that perspective in a way and that can help you provide input to us. Second thing to leave before we get there is you saw the concept I laid out with the cloud picture and feedback mechanism, streamline review, there are so many components in there that we are not talking about today. But that doesn't -- that shouldn't limit anyone of your groups or any one of you to start saying that, 'I have ideas about that,' even after you leave the conference, 'I have ideas about that.' Make sure that you put those ideas in something that we can sort of use and put it to the -- give us to the docket -- put it into the docket. We will take them. We'll take those ideas. We'll take those thoughts. If you have ideas about how best to review software,

which is not in a -- in a summation format or some other format or you think about mechanisms of reviewing is better and this is kind of information that we would -- it would be beneficial -- or how to review, let us know. I think we're looking for that, truly looking for that. So, I'll turn it back to you now.

MR. RITSCHER: Thank you. I'm David Ritscher with Cambridge Consultants and with a large entity, you know, that are going to produce many medical devices, clearly precertification would be valuable. But people mentioned yesterday, you know, if you're a little startup you might have one year of runway and you're only going to try to get out one product. So then it -- I'm wondering, first of all, is -- might a precertification program actually add an extra burden? You're going to have to do the precertification program and then you're going to have to do whatever the approval process is. If you're only going to release one product, might that be more burdensome than another group and do you -- my question is,

do you envision not everyone will be precertified in the long term? It will only be for larger entities or when -- when would one be precertified is my question?

MR. PATEL: Great. Sort of -- what I'm read -- what I'm reading between what you're saying is, are we presuming that only certain groups will be precertified? The answer is no. The answer is not to let -- exclude people from this. And this is what I said, that we're designing the program to be all inclusive. So, if we are not starting off saying that we -- the program will be only geared towards certain populous (sic) that we're -- we're looking for, that's not the intent. I -- I think -- I think the way to sort of answer your question about if -- are people going to be part of the program or volunteer. So, this is a voluntary program. This is -- we started off saying that this is a voluntary program. If you want to get it -- we are trying to create a different experience. We started this idea with this -- with the concept of, you know, the idea of

pre-check. If people are in the TSA pre-check line, they get a different experience going through it. You still get reviewed, you still get inspected. But you -- but you get a different experience. That's the experience we're trying to create, is what is a different experience look that -- that is so close to what you do in your day-to-day business operations is really where we want to get to. The closest we can get to recognizing how you manage control and deliver products in the best possible way is really where we're trying to get to. How do you sort of do that and that's -- so we're not even thinking about, you know, the dimensions that you were just raising, like is it one product or -- I mean, it's a choice. Seth?

DR. CARMODY: So, from the email box we have a couple questions here. Some requirements such as DHFs, et cetera, do not add value for some Software -- Software as a Medical Device products. Does the precert pilot include consideration -- consideration of these requirements, how would

this be socialized through the agency?

MR. PATEL: We have a journey ahead of us and I think we touched upon that yesterday. Education, socialization and training is built into that. I think we need -- we -- what we are -- where we are today is recognizing how close we can get to -- or the closest we can get to without getting mired into day-to-day operations, but recognizing those day-to-day operations that are valuable. So that -- that may take you -- take that DHF discussion to the next level, I can say there's many other things that the organization does that, you know, for being excellent, that can be recognized. Now, yes, we do have a transition that need to made (sic) -- to be made from recognition perspective. Internally, externally and -- and other places. So how do we get there, that's the journey and if -- and I'll be open to sort of ideas of how to get that socialized. I mean, we do -- we are actually thinking about implementation plan of how do you take this to actually implement it and tie it into our current regulatory structures. So to be -- to

be defined, how to do that, but we are planning on doing it. Great.

DR. CARMODY: And how would data collected from clinical trials from software devices that go through the precert program be viewed in regulatory submissions?

MR. PATEL: This is the discussion we talked about, about NEST and I was thinking about how do we sort of take that information and be reused, so there is enough efficiencies and evidence that's created and how -- and you see efforts in the Center from patient preference information to clinical evidence that is generated elsewhere, information, to real world. So, we have those efforts going on in Center and Jeff talked about that yesterday. We need -- we need to take a -- this program doesn't stay in its isolation. We are taking all the lessons learned, all the things that's happening around in the Center as well and integrating and making it tailored for this world of digital health and software, so that's how I would think about this. Would -- would that make

sense, Jeff? Yeah. Do we have -- are we good? Thank you. And here's my call for today, roll up your sleeves, head down and many people ask me like, 'Give me more details.' You're going to get so much detail -- I should not have used that word, sorry. Damn it. It sounded like -- no, never mind. I'm not going to go there. Please -- please roll up your sleeves, your sleeves today, engage and don't be hesitant to sort of tell us we're -- what we're missing on things. So, the three break-out sessions, Marisa's going to walk through the details of that. But really, we want your input to this. Help us build the -- build this program to the next level, thank you.

MS. CRUZ: All right, welcome everyone. So, as Bakul said, today is going to be interactive. It's going to be engaging. It's an opportunity to really hear from you about more of the meat of the program, what this is really going to look like. You've each been assigned to a break-out group and -- which you can find on your name badge. And you will return to the same break-out group, the same

moderator and the same location for each of the three break-out sessions. Break-out room assignments will be shown on the screen after this introduction and maps for the break-out rooms can be found at the bottom of your agenda. This information will also be displayed on posters and signs in the lobby. In general rooms A, C and G are located just across the hallway from the auditorium and balcony rooms 1, 2 and …

(A break was taken.)

MS. CRUZ: Okay. So we're going to call groups up in pairs. And so we'd like the person who is doing the read out from Groups 1 and 6 to come up on the stage along with at least one facilitator from Groups 1 and 6. You are in Group 1 and 6 if you were focusing on leadership. You were in Group 1?

UNIDENTIFIED MALE: Yeah.

MS. CRUZ: Yes, okay.

UNIDENTIFIED MALE: Where's my facilitator?

MS. CRUZ: Who was your facilitator?

UNIDENTIFIED MALE: Cathy.

MS. CRUZ: Cathy's here. Cathy, can you come up? And Group 1 …

UNIDENTIFIED MALE: (Off microphone).

MS. CRUZ: (Simultaneous speaking) So Group 6, any -- has Group 6 returned? Okay, there we go. There we go. And Vizma or Binoy, can one of you come up? Okay.

UNIDENTIFIED MALE: You are way cooler than we were. Is Vizma coming or …

MS. CRUZ: Binoy.

UNIDENTIFIED MALE: Are you going to be …

MS. CRUZ: Mm-hmm. Okay. So, we're going to approach the share and review by having, as we've done here, a reporter from each group, each of the paired groups as well as a moderator from each of the paired groups come up on stage. We're going to have the reporter read out the kind of five or so key takeaways or points that the -- that the group came up with and then we'll have the moderator just remain on stage for a few more minutes to have some open Q and A with the audience, okay. If people have questions, either

virtual participants or here in person, please feel free to come up to the mic or to give your question to a partner. Okay, with that I will turn it over. Do you want to introduce yourself and give your …

MR. REED: I'm missing my moderator, but I'll fake it for the moment. My name is Morgan Reed. We were with Group 1. We had a very interesting and lengthy discussion. I'm glad to see that all of you worked really hard with the post-it notes. I'm going to incorporate a lot of our thoughts. There she is. I'm riffing while I'm waiting for you to come up. So, basically since we were covering leadership, one of the areas that's very difficult is almost immediately our group went from the concept that the -- the five principles were great from a platitude's perspective and that they did speak to the larger questions about leadership. But the real questions and nitty-gritty of our group focused on how do we create indicators or metrics that provide for that outcome? There were some key things that -- terms

that we thought needed to be added under the characteristics of excellence. One of which under -- leaders actively engaged with all external stakeholders including patients, health care providers, caregivers, healthy users wishing to engage in preventative care, two elements were mentioned that the -- the concept of external stakeholders should explicitly or in some other way recognize regulators and pairs as external stakeholders. Another concept that was highlighted is we need a definition of what a leader is and recognition that leadership between a company of 12 people and a company of 10,000 can look very differently. And so the engagement metrics that the FDA would come up with around engagement need to recognize that difference. Specifically, the vignette that was spoken to in our group, that several people brought up, is in a ten person company you might be sitting across the desk from the CEO and next to the CTO. So, if you -- if -- under the concept of indicators number one was number and diversity of channels used to

communicate and reinforce commitment to core principles. Well, in a ten person company you have the channel of speaking across your desk and the channel of speaking to your left. In a 10,000 person company you need to have a -- a clearer structure and a clearer designation of those channels. So, we would encourage the FDA or any metrics that are developed to look not specifically at the -- at a number. It can't be do you deal with ten people internally or externally. One of the other areas this -- and the same number and diversity of channels used to communicate and re-enforcement and reinforce core -- commitment to core principles, bifurcates between internal and external and that goes to an area that -- again into that external stakeholders' conversation. Our group that covered product quality focused very much on demonstrating and creating indicators that are feedback loops for metrics that are measurable in terms of how do you engage with a patient group, how do you take that information back in and then

how do you demonstrate that it was effectively utilized. The suggested methodologies for doing that include surveys for -- for internal purposes and for external purposes, what -- it's a broader methodology in which you can reach out to patient groups and receive information. One of the obvious elements that came up was user testing and that would include both direct AB testing as well as focus group testing. So, those go into the metrics -- are you guys -- I know she's still typing. Under -- under the other key points that I -- that came up were -- when it comes to ensuring the organization's flexible, agile and manages change effectively, one of the areas that -- that was the largest amount of debate in our group was how do you build it into the culture of your employees, how do you demonstrate it? One of -- one of the core messages is that are your employees aware of it and how do they communicate it if you're -- if they're asked, hence internal surveys. One of the other objectives was how do you demonstrate that you make it part of their

objectives and end of year review. One of the examples was brought up by Joanna in our group is, she said that every year when she does her end of year review, there is a question on her end of year review that says, 'How have you incorporated product safety and patient safety into your job?' and the next question is, 'How was that recognized by your manager or leader?' So, there are ways that the FDA can use specifics, do you incorporate questions such as these, exemplar, exemplar, into end of year review. So, there are methodologies that -- that the FDA can create. And again, they will have to be more vignette based than sheer number. There was definitely push back in our group on the idea of having a hard metric, either on patient -- direct patient engagement or on how many channels you use or how you directly engage. So, the big takeaway for us is we've got to find how you -- leaders -- what does it mean by leader in these terms and then how do you show those channels of communication to leadership.

UNIDENTIFIED FEMALE: Thank you.

MR. REED: Did I miss anything?

UNIDENTIFIED FEMALE: No.

MR. REED: Okay.

MS. CRUZ: Okay. Excellent. Our other leadership break-out group?

UNIDENTIFIED FEMALE: Okay. So Team 6 looked at all the five different categories and I think in general we basically said that not one size fits all. And there's small companies, large companies, very structured companies and not structured. I think in general we said that you need ongoing training for not only product quality, patient safety, clinical responsibility but also cyber security and then you also need to make sure that you have competence in general. And across the board, across all the five excellence principles you need to ensure that you have effective communication. I think that was really key. Specifically, I think we said that for product quality, it needs to be incorporated as part of the missions and values to ensure that patient responsibility is more important than

profit and then also to have the right structure for validation, external and internal, and to ensure effectiveness. I think we also had the bus factor, which I've never heard of it in that way, but basically, I guess if you -- your staff or your project team gets hit by a bus, I think that's what it's referring to, that you're sourced properly. I've never heard of it in those terms, but -- it's a little morbid but, okay, good. Moving on. So, I think for patient safety, we said that we need to ensure that there's a mechanism for reporting as well as to ensure that there'll be resources to deter patient related threats and to ensure that we have a severely -- severity related model for patient illnesses, I think. Yeah, issues. Okay. And then for clinical responsibility, we need effective two way communication and that concerns are raised and acted on by leadership. And also, that we need to have a menu to select from to choose for the metrics for cyber security, we need your usual transparency via surveys, stakeholder integration,

a feedback loop and then subject matter expertise and for a proactive culture, we need to ensure that there is a feedback mechanism and that leadership does their own evaluation to understand when it's needed to do their own improvement and enable current investments and again focusing on the patients. So, I think the key themes or flexibility, subject matter expertise, not one size fits all, we need to resource properly and do everything else. I think that's the -- that's the take home message. There's no magic pill for sure. Thank you, I think.

MS. CRUZ: Thank you very much.

MR. REED: I would want to add that -- to recognize some of our other folks, you hit on a key point that we did talk about and then I kind of muffed over, which is the idea of risk assessment, the red, green, yellow, how do you build risk assessment into it. We had a pretty lengthy discussion about the idea of how do you -- how are you demonstrating and how do you create metrics around how you identify the risk, how you

deal with the risk and how you either mitigate the risk or -- or make sure that your employees can communicate that risk internally. I think that was one that you mentioned that we did too and I want to recognize our team, who also agreed.

MS. CRUZ: Great. From a process perspective, do the moderators want to comment on anything that went well or lessons learned from the first break-out?

UNIDENTIFIED FEMALE: Well, what was wonderful in our -- in our group is that we early on identified Morgan to step up so that it really is community based creating all of these characteristics and indicators rather than, you know, FDA standing there and, you know, having that -- you know, FDA at the front of the table or the front of the -- of the room. It was actually the community member at the front of the room. And we had -- each of the groups were very active, if anything it was very hard for them to just look at the characteristics without already diving into the indicators. So, in many ways the two parts to

the conversation were very tied into each other. So -- and as a reminder, this is the beginning, it's iterative, you know, the information that came from the pilots. Now this is the next tenth pilot and this is an iterative process, so I think that there was a lot more conversation that could have taken place, if we didn't have the time -- time stops in between.

UNIDENTIFIED MALE: I'll just add, we -- we -- we had a very similar experience in ours. I mean, we -- you know, we started out, you know, by saying this is about you, this is the tenth participant, you know, this is the tenth pilot participant for us and we wanted to make sure that we were engaging across the entire spectrum of stakeholders and so we made sure that that's actually what we had. And, you know, it was nice to actually see that -- that spectrum represented in the group, we had industry, academy, we had government, we had patient groups, we had provider groups, we had health assessment organization participation in there as well. So, we actually

had the full -- you know, full grouping and we were able to divide into the different excellence principles. And I think if we had -- had enough time, I think this could have gone on for about an hour or longer in coming up with different metrics. So, the thing I implored the group to do is after today, to keep thinking on some of these issues because, you know, as Janet (ph), you know, rightly said, I think what some of the struggles that we had were around, can this be scalable from a big organization to a small organization and there are certain parts to -- it's not necessarily so clear that that's actually going to be there. You know, one of the points was made that some smaller organizations really don't do assessments of their employees because there may only be three of them. It's not really that necessary. So, you know, making sure that those was -- you know, that's a capability that we can actually scale to, so I asked my group to make sure that when they leave today, that they continue thinking about the issues that we brought up as a group and send

those to us. I'm happy to receive them. Vizma would be happy to receive them. Marisa would be happy to receive them. We really want the input. We really want to get your thinking and your hard thoughts about these things. So, if there is a way for everyone -- I'll just say this broadly. If there's a way for you to keep thinking about what you came up with in your groups do so and send it to us.

MS. CRUZ: Thank you. So, I think we only have another minute or so for this group. But is there anybody who has any questions about the leadership category of enablers that they'd like to address to the folks up here on the stage?

MR. FARANESH: Can I go to a mic?

MS. CRUZ: While he's walking to the mic, I'm just going to also just say that many times there's a conversation of small, medium, large companies. But the reality is the small company doesn't stay small and it's not something that just happens overnight. There's that evolution. And sometimes we need to think about this from an

evolution perspective rather than a jumping up steps.

MR. FARANESH: Thank you. My name is Tony Faranesh. I'm from Fitbit and I'm just curious. In your group, was there consensus at the end that this was a tractable problem to devise -- to come up with characteristics that would apply across the board from a small company to a very large company or companies that have track records and have license to (inaudible) already?

MR. REED: I think -- so what was interesting is right at the very end, which is why we needed a little bit more time, there was a move by the group to recognize that there may be ways, so long as the FDA doesn't create actual metrics. Meaning that if it -- if, for example, patient engagement is 'show us how many patient groups you dealt with,' well, that doesn't work because maybe your product only meets the requirements of a thousand patients, it's a very niche product. 'Or you must show four channels inside of your company on ways you can communicate about product safety.' That

doesn't work. So, it was more about 'can we create metrics that show, here are the channels available, this meets a quality metric because it is -- here's how the path to -- key decision maker or C-suite or other leader is -- is in the mix. So, hard numbers, no. If those numbers are instead qualitative rather than quantitative then, yes. I -- I would look for any in the group who's going to shake their head no, but right at the end that was kind of the -- where it was getting to.

MS. CRUZ: Thank you. Okay. Let's give a round of applause to Group 1 and 6. Okay, our next groups are 2 and 7 who focused on people. Can the person doing read out and the moderator for those two groups come up to the stage?

UNIDENTIFIED FEMALE: We are Group 2 and our task was on people. So, we brought a lot of people. And rather than read off everything that we did, we just made a -- a visual. I'm sure you can all read it. No? Okay. So, we started off the exercise looking at the excellence characteristics and we had all of us as a group

think about what excellence characteristics for people would resonate most with people or what they felt would best describe excellence for a company. So, our top five that we came up with, paraphrased in very small words and not nice sentences like in the packet, are training. Not only training of people when they come on but continual training and knowledge -- management knowledge of what people know, what they need to know to do their job. Communication, being able to have good communication and -- and being able to report issues through the organization. Diversity, diversity in groups meaning that your hiring practices makes sure that you are hiring the correct people with different perspectives for the product that you're trying to make. So, you make sure that if you need a clinical person on staff that you hire a clinical person with the appropriate background. Empowering people, which is similar to what is the -- the third bullet in the -- the predefined list and accountability and being able to give feedback. So, now we are going

to have each -- a representative from each of the excellence principles talk about the objective indicators that they found best met one of the excellence characteristics. So, first up we have product quality.

UNIDENTIFIED FEMALE: So for us we looked at people -- the product quality aspect of that and we looked at identifying competencies of who needs to be in the room for a cross functional team. So not having it driven by we need these six people here, but we need these eight competencies here and who are we going to find really in our staff to make sure these competencies are represented across the board? We're also -- then the second one was looking at accountability. So looking at -- ensuring that a structure of accountability and responsibility is well defined and documented. What works for an n of few will not necessarily work for an n of many, so it's hard to be able to say this applies to every type of organization type. But ensuring that that documentation is there to really make sure that people are focused

on accountability, responsibility across the board, that's what we're looking for.

UNIDENTIFIED MALE: So, our subgroup, we were looking at the patient safety enabler and in regards to hiring practices we thought there should be an indicator that specifically considers your staff qualifications. We had a lot of conversation as to how do you ensure that you have the right clinical expertise or the right cyber security expertise or the right human factors expertise when considering what it is for your -- your particular product. And so there should be some sort of indictor or evaluation of how you are bringing people on board from an education perspective or a CV or whatever their experience is. We had a lot of conversation on this about small versus big as -- as well. And I think one of the themes that kind of kept coming out is while we could describe a -- a what -- and I think I'm hearing this with a lot of conversations with KPIs and indicators, the -- the how that is determined is going to be varied. And so there

was a lot of conversation with that. And regarding patient safety and communication/reporting issues, we thought one of things that ought to be considered in this program is 'What's your escalation path?' and specifically with software, we used the term a couple times, the speed of software, how does that -- how does that communication for a patient safety issue, how quickly does that get escalated, where does it get escalated to, how quickly is it -- is it resolved?

UNIDENTIFIED MALE: All right. So for Group 3, we were looking at clinical responsibility and the two areas for clinical responsibility that jumped out at us were diversity of feedback and accountability. So for diversity of feedback, we thought it was very important from a clinical perspective to look at premarket and post market feedbacks. So, we know the premarket or the voice the customer feeds into that development activity or from a post market perspective and certainly through the complaint process, you want to understand how the device is being used, what is

the utility of the device and do you need to make changes to the device to meet the intended use or the needs of the patient population that you're addressing. So, that's the diversity of the feedback from a clinical perspective, both premarket and post market. The other piece of it was actually looking at accountability. And for us, when we look at clinical responsibility and accountability, we dovetail that with the people segment of the activity. We're really looking at how do you assess the individual and for us, a 360-degree performance assessment really makes sense because not only are you going to look at the what, so how did the employee actually complete the objectives or the what of their activity, the deliverables, but also the how. How do they work with the individuals on their cross functional team, how do they work across the organization? Were they collaborative, were they constructive, did they really enable the organization and were they accountable for the overall activity that they were performing. So,

that was Group 3.

UNIDENTIFIED MALE: For the excellence principle related to cyber security is what we took a look at and the two that we sort of -- two characteristics we focused in on measuring with objective evidence were training and communication. So from a training perspective we first looked at some of the traditional measures that would be objective evidence such as training records or job descriptions for qualifications, but we also, I think, specifically around cyber security, look to a new perspective of potentially requiring continuing education coursework or credits for your cyber security team, just -- to ensure they're staying relevant on cyber security. And then related to communication we thought it's very critical that you have a mechanism for reporting, capturing, classifying bugs or issues related to cyber security.

UNIDENTIFIED MALE: So we in Group 2.5 because I like version control -- and just to be clear in Group 2 we -- we had many, many more Post-its, but

Linda was really cracking the rib -- the whip on how many Post-its we could actually put on this. So, training, communication, reporting issues, those kinds of things, one of the measures that we were looking at was accountability for escalating issues, not only accountability for the individuals within the organization, but also tied to MBOs or some other metric that managers or executive folks were responsible for. And we had a lot of discussions also about small companies versus large companies and -- and how those are going to be challenging on accomplishing those things because if -- if you're an N3 (ph) you probably don't have MBOs. Another interesting one that we had -- and again this probably is more attune to a larger company is identifying where within the organization the issue came from so that you could identify, are you actually getting issues communicated and people feel empowered to communicate them from across the breath of the organization. Diversity was the other one. And we -- one of the things that we had talked about

was whether or not the diversity within the company actually matches the diversity outside of the company. Those are two different measures really. You could look at an individual company and say that they are diverse, but they don't necessarily match the diversity of -- of the community at large or, you know, where they happen to be at. And then also is there a -- a diverse workforce and a thinking process that goes along and -- and we talked a bit also about diversity within an organization and how that differs and is more challenging to the measure and monitor and those kinds of things than it is gathering diversity on, say, a product development when you're going out and gathering diverse input from individuals. Both are important, but different way -- different challenges go with each to try to measure those. The last one there was empowering people. Again, you could also use the metric of where within the organization things came from, how many people actually brought issues to the front and are those issues being addressed, did

everyone weigh in. And not only do you have a process for empowering people, but are you actually putting resources behind that and supporting it.

MS. CRUZ: Thank you very much. Esther and team?

MS. BLEICHER: Clearly Group 2 was the extroverts. I represent the introverts for people. So we couldn't actually get anybody from Group 2 -- or from Group 7 to volunteer to do this, so I'm going to present. But we'll make sure we do that for the next round. We actually had quite a few of the same conversations and -- and -- and sort of same discussions that -- that they had. But one of the things that I -- so, I'll -- I'll sort of be brief and -- and highlight the ones that weren't covered. I think an important characteristic that came up that we felt wasn't represented in this list of characteristics was this idea that throughout the company there was this understanding of patient excellence. So, does every piece of your company know at the end

of the day the patient population that we're treating, the condition that you're treating, why we're treating it and have a very clear understanding of, you know, the 75,000 lines of code that they just wrote, how that impacts the patient's life or your customer's life and that that's included in patient safety but is very different, it's around patient excellence and that everyone has a very clear understanding of the, you know, the overarching patient that you're -- that you're taking care of. We talked about continuous process improvement so that it is continuous, that it's not just a one-time thing and that -- that -- that changes are made and that it is an evolving process around how people understand and work within your organizations. We talked about this idea of innovation, that, you know, there is a culture within your organization of innovation and it is recognized and it is accepted and that everyone feels comfortable to say, 'This is my job, this is how it matches back to the strategies and the culture and the goals of

this organization.' But I think that I would like to recommend ways that we can do this better, faster and safer and that innovation is recognized across the organization. We talked a lot about reward and recognition and this concept of what does reward mean and that that might be very different across organizations, big, small, but that -- that when you talk about reward and recognize that it's actually measurable and that it means something to people. It's not just a, you know, employee of the month because it's a -- it's a recognition that -- that a company just wants to do. And we talked a little bit about measurements and assessments of these characteristics and how difficult that is to come up with KPIs around these because it's a lot around, sort of, intangible culture and excellence and things like that and that within companies, big or small, how these companies choose to reward and recognize and to assess their -- their people might be very different, but that as long as there was a -- a process for recognizing and that it was

constantly evolving and continuing to be refined and that there was constant feedback from employees throughout your organization that -- you know, that was how we would think about measuring these -- these characteristics. And again we -- not to go into what Group 2 covered, but we did have a lot of the same sort of discussions that you all had around making sure you have the right people who -- with the right skill set involved and that that's across the board and that, you know, communication is up and over, not just down. So, we did have a lot of the same, you know, components. Did I miss anything?

MS. CRUZ: Thank you very much. Okay. So, very briefly, because we're running a bit short on time, any additional process, things -- things that went well or could be improved upon from the moderator perspective?

UNIDENTIFIED FEMALE: I think that, you know, Group 2 was very creative and very engaged and that is very much appreciated. We certainly were asking a lot of everybody to do this in a short

period of time and -- and you think very specifically about a topic, you know, and you know, it's like, 'Hurry up, come up with a gazillion ideas, it'll be awesome.' So, I think that, you know, as was said with the previous groups, we expect that you will continue to think about this and we welcome any additional thoughts, information that you have on this topic.

UNIDENTIFIED FEMALE: Yeah, I would just echo that, particularly with the metrics, I think it really reflected the experience we had on the pilot visits, right, where it was just -- it was a little bit challenging and took more time and we didn't have the time. But we started the conversation today which was great and would really like for your continued critical thinking about what kinds of metrics would be appropriate, could be scalable, maybe there's a set of metrics that makes sense for smaller and a set of metrics that makes sense as companies evolve, so keep thinking.

MS. CRUZ: Okay. Great. And any questions

for -- from the audience for the groups focused on enablers of people? Okay. I think you guys covered it, thank you. Could we have the -- yes, we'll give everybody a round of applause. So, moderators are going to read out for Groups 3 and 8, focus on strategy.

UNIDENTIFIED FEMALE: Alrighty. Okay. So we talked about strategy in our group and so about five takeaways for you. The earlier part of our conversation was rather existential, so we'll cover those first. We do want to recognize that there's a bit of, sort of, chicken and egg problem with the FDA evaluating strategy because for many of us as health care companies, what the FDA will or won't do or the lack of transparency around that is key to us formulating our strategy or challenge to us being able to formulate a good strategy. So, we just wanted to call that out, that there is some concerns there. Second, we question the FDA's right and ability to evaluate our business strategy and whether or not that's effective, so more scoping around the definition

of the strategy or evaluating is required. Moreover, we would believe that it would be nearly impossible to come up with universal metrics to measure a good strategy because you have metrics that evaluate whether or not your strategy is good or inherent to what your strategy is. For example, one of the proposed outcome metrics was -- - of a good strategy was that it was being incorporated into clinical care pathways that currently exist. For my company, we're actively trying to change those clinical care pathways. So, being incorporated into them, which means we're failing at our strategy, so that being a universal measure of success wouldn't be helpful for us. So despite these questions -- existential questions about evaluating strategy, we do believe that having a strategy and being able to articulate that is key to the success of an organization and is an excellent principle, fair enough there. So, that given -- given that when we were looking at what the characteristics of a good strategy were -- a couple of things that we

thought were missing from the definitions provided were that a good strategy is adaptive, not just to internal changes but as well as to changes in the ecosystem that you're operating in. A good strategy is communicated not just internally, but also externally and is part of how you manage your external relationships and finally must include a risk -- sorry, a risk assessment component, not just your business strategy but also to the entire lifestyle of your product. So sort of just summarizing all of that we came to the point of -- you need to have a strategy, we agree that's important, we're not really sure you can universally measure what a good strategy is. But that if you were going to objectively measure whether or not you had a strategy, the three tenets we thought were most important were, one, were you able to articulate that strategy. Two, do you have plans and processes in place to communicate that strategy to your organization. And finally, do you have a way within your organization to check that your strategy is

working and being implemented. That's it.

MR. AMOR: So Group 8 strategy was to have me present, which is a failed strategy already. So, next time we will have a non-moderator present. So, actually, it's pretty consistent with the -- the prior group's key takeaways. So, what we did is we looked at the characteristics of excellence first and then the examples of the objective indicators, so we kind of summarized the approach that way. Under characteristics of excellence, we thought that the first characteristic about basing organizational strategy on, you know, customers and health care -- folks in health care ecosystem, we needed a better definition of what customers are, what users are and other categories, so something that came out of that was potentially a glossary of some sort to help company strategize each of those product, you know, categories. We also felt that in the characteristics of excellence, we needed further detail in the actual health care ecosystem. So again, another terminology question, particularly in regards to

payers and patients. So, again there was a little bit of confusion about, you know, what is the strategy geared towards. Is it business strategy, is it strategy -- is it business strategy geared towards caregivers? You know, that's -- that's the type of thing that we looked at there. We noticed that there was a missing category in that excellence -- characteristics of excellence which was a focus on a technology landscape or a technological ecosystem so that included things like integration, interoperability. We thought that the -- the group mentioned really several times that it's not just about whether we can, you know, meet user needs, but we can meet other stakeholder needs in terms of easy integration into workflows, we had a lot of folks in panels yesterday talk about that if something isn't easily integratable within a currently existing workflow or doesn't make it easier or is difficult to incorporate, even if it's brand -- you know, completely novel that might really diminish the value. So we thought that that was something that

an excellent company would do. There was a very contentious or exciting depending on how you approach it, conversation about the FDA's jurisdiction, just similar to the other -- the other speaker about their assessment of business viability. So, the term business viability was brought up in our group and after much debate -- you know, there was two -- two streams of thought. The first stream was that yes, that might be important because as somebody in our group mentioned, I thought it was a good point, you know, we're investing -- you know, practitioners, payers are investing resources, capital into new products in digital health. And if that company is gone in a year that might be very disruptive to the care paradigm for those specific individuals. And another group had a counterpoint basically saying that the FDA had no business assessing business viability which is obviously a strong argument there. So, we evolved that conversation into less of business viability and more into assessment of a company's sustainability and

that's where we ended that discussion. On the objective indicators we thought that both sub -- subgroups believe that there has to be some sort of indicator or objective metric surrounding multidisciplinariness. I think that's a brand new term, but basically how do we assess. So, we've heard through the last few groups multidisciplinary input, cross functional input. On a strategy perspective we thought that -- the example given was if the VP of marketing sitting in a room making all the strategic decision making, that's probably not appropriate. So that's something that we thought would be a good indicator. More focus on cyber security, we thought that that category of strategy didn't really have any focal points on cyber security. We also wanted to emphasize excellence in human capital when making strategic determinations and we wanted to change the terminology. There was one indicator that says for strategy, high rate of customer adoption is a good objective indicator, but we kind of thought about several examples

where, you know, a change or (inaudible) in adoption is adequate or a high rate of adoption is maybe too generic to characterize. So, we thought that, you know, having some more definition or changing high rate of adoption to expected adoption or to increase in adoption or something similar would be more appropriate. And the last couple of comments I have are more general. I think two things emerged here, is that strategy seems to be one of those enablers that might be difficult to scale, to smaller organizations mainly because again if you think about just from a resource perspective a lot of the things that the characteristics of excellence you're asking of companies may be difficult to do when you have a one or two person company. However, we -- we did feel strongly that maybe this is one of those situations where it's a minimal threshold or a minimal floor where if a company is developing higher risk products, for instance, regardless of whether you're a one or two person company or a 20,000 person company, we -- maybe that's the

floor that you need to meet in terms of strategy. And the last thing that emerged obviously was concern about the -- you know, this is an overarching theme for strategy, one of the things that emerge was a -- a concern about FDA's jurisdiction and how to approach, you know, strategy, what exactly should FDA be looking at, you know, in terms of a company's strategy. Is it truly business strategy, business modelling? We -- you know, we strongly felt that that was maybe not in -- directly tied to the precert. So a little bit more information about what that is would be very helpful.

MS. CRUZ: All right. And so again turning to moderators? Okay. I was the other moderator for Group 8. Anything that worked well in terms of process, any lessons learned from the conversation?

UNIDENTIFIED MALE: First off, I'd like to -- I'd like to thank everybody in my group. They made my life easy. They were very participatory, very engaged. I think what I learned most

importantly, we need to continue to have these kind of discussions because we were just getting warmed up. And I think we need to figure out a way to do that in the future. I heard an interesting concept that didn't get mentioned, was this digital health strategy, that would be a separate part of your strategic plan where you're sort of thinking about the problem that way and then you can integrate that back into your existing strategy. So I thought that was very interesting. That would include product, customers, clinical (inaudible) application, all those kind of things.

UNIDENTIFIED FEMALE: There was also a comment about culture and that integration -- that feedback does relay back to the culture of the company. And I thought that was a good highlight. It is part of the triangulation that I think Bakul mentioned. So one aspect leads to another, it comes full circle. You can see it in another part of the metric. It's not just isolated in and of itself. That's what I meant by triangulation.

But I think -- thank you, group. There was a lot of good input. We had a smaller crowd and I think the majority were able to each say something. There was lot of questioning on, yes, should FDA be looking at strategy, certain aspects of it, how do we look at the regulations behind it and again, I encourage just participants to keep in mind that that will come. But at this point we have to generate the conversation first.

MS. CRUZ: Perfect. And I don't think I have too much to add. I would definitely echo David's point, that our group struggled with a number of aspects of the terminology that they -- they pointed out that there's a fair amount of room to go in sort of crystallizing how FDA is thinking about these terms and then how the broader kind of digital health community is thinking about these terms. So, that was -- that was definitely a takeaway for me. Okay, can we give everyone a round of applause from Group 3 and 8? Okay, read out and moderators for Group 4 and 9, focus on partnerships and resources.

UNIDENTIFIED MALE: So I guess I should -- I'm going to start by saying that I felt like I drew the short straw on this topic. But the dialogue was actually quite amazing. So, I think my first point would be around community. This was definitely a community discussion. I think the moderator and -- and FDA both did a great job of attempting to steer us. I think we got a lot of the ultimate goals out of it, although I think someone earlier just said it was a warm up. It was absolutely just a warm up to the discussions to come. Four key points I think that we took away from it. The first, the way these frameworks are written, I find that they're often hard for people to understand how to use them. I have personal experience with CMM 1.1. I remember going through that process and everybody looking at that thinking, 'But I don't do this, I don't think this makes sense, but I got to do this because it's there.' And I think we saw that in the discussions we had there and the idea that sometimes these things don't make sense and your

business doesn't come out, right? Or how to -- or how to handle it doesn't come out and so a couple of lines of thought that developed there, could we look at how we word these to make it a little -- a little clearer, that this isn't just a checklist or, you know, a spec that I've always -- that -- it's hard to say enjoy specs. But a spec that I've always appreciated was TIR36 because it had all the specifications section, but then it has a lot of tangible examples that -- you can't always use them identically, but it gives you, sort of, a form of reference for interpretation, right? So, that was definitely something that you saw come up over and over. Everything -- you know, the idea that yeah, this still could apply to you, but it applies in a sense that you say it doesn't apply. That doesn't -- you know, that just doesn't seem intuitive to people and how you say that is not always clear and I think -- I've experienced in -- in different size companies, I -- you know, what actually gets me to my second point, which is it was less about large and small in many ways as we

talked through this. The differences in -- between hardware and software were far greater than the differences between large and small. I'm currently at a very large organization and I can say that many of our -- I struggle every day with making software in this regulated environment, right? And I'm not -- I'm not personally convinced the differences are as great between large and small, we -- in this -- in this particular sub category I think we're going to have a lot of the same struggles, right? A large company may have more structure, may have more resources, those resources actually just bring more paperwork often than -- than benefit. But we all struggle with the same thing, you know, how do we -- how do we know that what we're doing meets what's needed? How do we -- how do we know it meets what's needed for the FDA? You know, there was a comment earlier about -- on the strategy section about transparency from the FDA. This is, I'd say, one of my daily struggles, is, you know, we think we're doing the right thing, but is this

going to satisfy? And that's what kind of unique about this program, is that hopefully by doing the right thing we are satisfying. One of the things that came out, a comment that I really liked was the key here is evidence of a thoughtful decision making in terms of suppliers. And I think, you know, when you strip away the bureaucracy that's really ultimately what you're trying to look at and a small company can do that. You know, a large company would probably have a lot of bureaucracy around it which creates structure, but a small company can do that as well. You know, it's just a matter of having a criteria for your selection and just writing it down and showing that you did it, right? There's some interesting conversations around whether you have all the criteria upfront or whether it's okay for that criteria to come later through usage and -- and where that would sometimes apply, maybe sometimes wouldn't. And so, you know, which really -- which goes onto the next big observation. One of the things that was clearly unique about software I

think compared to what -- when you look at existing regulations, you look at how it's approached is that software is a lot different than hardware. We have -- you know, just the number -- we talked about the fact that part of the challenge in the space of -- of resources and partnerships is we have so many different types of partnerships and software. It's a lot different than hardware, you know. We had everything from open source to, 'I bought this library and now I have it and that's all I really need to know and if they go out of business I still have it,' to 'Software's a service where, you know, the continuity of that company could be critical to -- to the care continuum,' right? And this -- this looks really different than the hardware space looks. So, you know, as we look at this -- the criteria, we have a very -- we had a very interesting set of criteria that didn't all -- it didn't look at all like the hardware centric criteria that I think made it on to the examples. But even in there they're going to look very

different depending on the type of partnership and type of engagement that you're pursuing. So, that was I thought very interesting. There was also some -- Robert -- and I'm sorry, Robert, I don't --I know we exchanged emails, but I didn't get your last name, had some really interesting parallels to the auto industry that he was trying to bring up in terms of how we might model this. So some really interesting conversations to look at. Are there other regulated environments that could give us some guidepost for -- for this type of engagement. And actually, I'll just end with that -- that sense -- you know, this really was a community discussion and that sense of community, you know, we started exchanging emails and contact information. So I think that's -- that's a sign of a really, really big success of this -- of this day, that, you know, we're not only bridging the connections with the FDA, but we're actually starting to bridge the connections between ourselves and large, small, start-up, established, so …

UNIDENTIFIED FEMALE: Okay. So our group also discussed partnerships and resources. I want to highlight some of the takeaway points that our group discussed. So as going through the characteristics of excellence, we noticed a common denominator among them. So we decided to include that as an additional characteristic, that being sustainability. We also discussed that not only do these characteristics should -- should they be properly managed, but they should also be well developed and maintained and that there be transparency. We agree that all of the discussed characteristics meet the five excellence principles. We discussed metrics of partnerships and resources. A few key ones are number of partnerships, quality of the partnerships and diversity of partnerships. An example of a measure of the quality of partnerships, for example, would be, say, a scorecard for that partnership. And we too recognize the challenges of assigning objective indicators to startups and smaller companies. It's interesting. We -- we

discussed the -- the size differences among the organizations. But just touched upon the differences between the software and hardware differences, so that'll be an interesting discussion to take back with us at the next -- next session. But one of the -- one of the characteristics that we thought may not be applicable for, say, a smaller start-up company is when evaluating finances. And so we thought of additional indicators that may be more applicable that could be reviewed such as budgeting and forecasting, planning for funding or other indicators of financial strength and foresight. We agree and I think this was alluded to previously that a small company doesn't always stay small, so that there should be an organic sort of evolution of these objective indicators and this can only be achieved through a well-documented, well-maintained process with continued transparency. Thank you.

MS. CRUZ: Perfect. And the same questions, any lessons learned from the moderators?

MR. VICENTY: So, actually, yeah. We had a little different dynamic when we started the discussion in the session. There was a suggestion originally about breaking up the team, as opposed to the original plan, to small and big manufacturers to really start to get that dynamic and perspective. And I think the -- the whole consensus was, no, let's just work together as a group and get that stuff out there and I think the evolution of that really allowed some really great discussions and really great perspective. And even within the community itself to really understand that there isn't necessarily a difference in what's being asked for or how it's being -- or -- or what these models can get to, it's the execution piece, right? Different concerns, different elements, different demonstration of it that I think is really what drove that. And I think that -- that understanding and alignment coming out is a great takeaway for just the general discussion about small and big manufacturers. This -- these

concepts apply, the way you do them may look different, but it's still visibly there. One great example -- and this is actually something that came up with regards to the excellence principles themselves within this space and in regards to with software versus hardware, somebody brought up the idea that maybe an excellence principle that should be considered an extra characteristic is, 'What is an effective, maybe more continuous monitoring strategy for your suppliers? Do you have something like that in place? Can you respond and react to it?' So, the concepts came back to again an idea of how do you measure and monitor your ability to -- to respond to situations and keep an eye on that mode versus prescribing all that criteria upfront? So, that was a -- I thought something that was a really good takeaway to bring back and consider because it touches there. And I think a lot of discussion also helped, you know, when people started breaking down what these elements were, how they link together, right? Some of the elements that

fall into strategy would feed into what happens in the partnership management or how you develop even your plans to manage that specific partnership. So, I thought there was a lot of great insight there. We didn't get to discussion of some KPIs, but I think two things that I would at least take for discussion later for anybody in the other break-out sessions is, one, all options right now are on the table, right? We are in the early stages of a lot of this design, so don't limit yourself to what, you know, you think can or FDA will or will not do. It really is an open -- an open blank slate for what makes sense. It's just if we're suggesting one thing, then there's got to be some other checks and balances along the way to -- to measure up with that. And then the last one would be the -- just the idea that these models -- because this was a big confusion point, they're not intended to be what FDA necessarily is going to come in and look for. We're not going to look into all your finances, but we want to understand, is it an excellence principle that you factor that

when you look at your suppliers at least in this category? So, help us, you know, figure out -- backtrack from these activities and what's in these processes, what it is exactly that we would care about from the assessment standpoint in some way, shape or form.

UNIDENTIFIED FEMALE: So, similarly in our group we had fewer people than we had expected to have originally. So it made it nice because we were able to have a more intimate conversation. We looked at the distribution also of our group and we were highly skewed towards larger manufacturers with fewer smaller developers in -- in the audience. And so I think the conversation was definitely enriched by having everybody participate together. One of the things we did learn and think about at every single stage for every single excellence principle as well as all the characteristics of the enabler is how does it fit for small versus large companies? And we found some -- some challenges in some cases with how to put that together. And our group spent a

lot of time discussing that. The other thing we found as a challenge was language, how we defined each of those different characteristics from what does partnership even mean, are we talking about formal or informal partnerships? Who are all the parties when we think about a partnership? So -- so those were things that we actually discussed in our group and -- and alluded to in prior discussions that language probably needs to be flushed out a bit more so that we're all speaking, using the same terms and understanding what another is -- is meaning in that conversation. And the last point, I think we had some really creative ideas of ways to find metrics that may fit better for smaller businesses, particularly ones that may not have a product yet but are in the process of developing their product such as Angel Investors and what -- the score they would give them of the audits, things of that sort, that would be an alternative metric for the small businesses compared to the larger businesses.

MS. CRUZ: Thank you very much. Any burning

questions for the groups focused on partnerships and resources?

UNIDENTIFIED MALE: Yes, I had a very quick question though. You both addressed this question of, well, hardware's very different than software. But given conversations at the Morgan (ph) conference and Alpha Conference, what we just talked about, other than tongue depressors and Q-tips, I feel like almost every medical device is software. The software part is inculcated into almost every single medical device that I'm hearing about, being hyped or being talked about. So, when you said there's this huge difference between partnerships, et cetera, on the hardware versus software side, I feel like that's -- we're getting really close to a blend with almost every object. So, did you guys talk at all about that in this -- on the differentiation of partnerships?

UNIDENTIFIED MALE: We definitely didn't talk about the blend. But I mean I do work in devices -- I -- I work in pure software devices as well as devices that are mixed and, you know, the hardware

stuff is still there. It makes sense -- what I see for the hardware side makes sense, but it's clear these regulations were developed before software existed. And so a lot of decisions we make, it's -- they just don't -- or the way we manage that work just doesn't fit into the kinds of things that existing regulations are looking for, would be how I'd look at it and I think -- I struggle with this even (inaudible)embedded where hardware is a consideration. I struggle with the same problems that I struggled with when mobile applications were developing. There's -- there's more similarity than difference in the struggle and it's all related to -- we're not talking in software terms yet.

UNIDENTIFIED FEMALE: Sure. Yeah, I just want to add one point that we -- we did discuss during our session, was -- I mean, I agree with you completely. However, the -- I guess from personal experience, what I can comment on is that often times the software groups and the hardware groups, the developers themselves are working on two

different timelines and that coordination needs to be there. Additionally, we discussed that upfront, that there needs to be a proper plan and that plan should include a communication plan to the customers and also -- you know, if any training or whatever needs to be included in that, should all be decided upfront. And another thing we -- we talked about was, you know, technology subset and planning for that ahead of time.

MS. CRUZ: Perfect, thank you. One additional question.

UNIDENTIFIED MALE: Yes. I wonder if you have a (inaudible) that the overall size of this exercise should at all be restricted. It seems that we're talking about small and larger companies and we want a model that fits both. But I also wonder if we shouldn't aim for an exercise that is actually doable for both, you know, large and small and the idea that you're building a way to measure the excellence could, you know, give work to all the consultants in this group for the next, you know, ten years. So I wonder if it

wouldn't be useful to put a limit on -- and I don't know how you do that, but to put a limit on the overall size of a precertification.

MS. CRUZ: Okay. I think that's -- unless you have a comment, Bakul, I think that's probably just a comment for the -- for general consideration for our group?

UNIDENTIFIED MALE: (Off microphone.)

MS. CRUZ: Sure.

UNIDENTIFIED MALE: I would just say that -- you know, I would just say that FDA wasn't in there telling us what to do. They were really -- 'tell us what makes sense' and so certainly I'm looking to limit the impact on my organization that slows down development in progress. So in some ways I think maybe this -- this process is leading us in that direction already.

MS. CRUZ: Thank you. Let's give a round of applause to Groups 4 and 9. Okay, and our last pair of the day, Groups 5 and 10 focused on processes.

MR. MCFARLAND: Yeah, thanks. So we were

talking about process. I'm from Group 5, Ian McFarland, Pear Therapeutics. And we kind of started by looking at all these terms and I think everybody in the group felt that they kind of were vague. It's almost a projective test about -- you know, everybody wants excellence, everybody wants value. But I think one of the things that came up really quickly for us is how would you measure this, how would you look at the set of criteria and apply it across companies and come to something that was digestible and understandable, that would inform clinicians, that would inform patients but also of course would inform the agency because I think there's a duality here. We're trying to build a bunch of criteria that the agency can evaluate and make transparent and decide whether or not we've achieved excellence. So we kind of started by treading a lot of this, trying to get away from what Howard from the (inaudible) scorecard called weasel words, like what was one of -- value I think was one --

UNIDENTIFIED FEMALE: Optimized.

MR. MCFARLAND: -- optimized, yes. Like, total consultant words, right? So I've been a consultant. I've used these words, hopefully not in anger. But so we really tried to go back to, 'What are we trying to accomplish?' and I think we distilled this down quite a bit. We really focused around delivering meaningful safety endpoints and meaningful -- like, the question of safety also kept coming up as like -- I think a lot of folks felt that the precert program -- I mean, it's really about the manufacturing practices primarily at this stage. But this question of safety and efficacy keeps coming up. And -- and obviously that's kind of a label claims question and obviously that's going to be a later stage. But I think when we're thinking about the processes that are going to deliver that kind of value we really wanted to get into that. So we kind of -- I put these up just because I thought it's useful to look at the actual words we came up -- we spent a lot of time on the words for this stuff. Really trying to focus on products and

services that develop -- that are developed and developed, promoted and marketed to deliver value according to the intended use. And I think intended use was also one of these things that kept, sort of, slipping out of our thinking about the process. The word value, we kept, like, stumbling on it and I'm sort of jumping down at the bottom here. This idea of what value means, I think we kind of need a new word and a -- like almost a defined term to talk about what we mean when we mean value. I think it's really important for us to care about patient safety, efficacy, appropriateness for intended use, cyber security, a whole set of things that aren't just like business value, they're really patient value -- patient value expressed in -- across a multiple axis. There was a whole big side discussion about whether the agency should care about business value. On some level, economics enforce business value -- and I think there's a duality there too. I think, like, the idea of continuity of care is a really significant consideration and I think it is

actually valid for the agency to say, 'Well, okay, we're going to let you put this out, but we need you to be around long enough for patients to use you and you're -- you can't just disappear in the middle of treatment.' That has a real impact on patient value. So we spent a lot of time with, sort of, going through all of these different terms. But -- I've gone through the other -- sort of other three framings that we came up with for -- for processes. We're also really concerned about user centric processes used to consistently produce safe and effective products, systems and services that meet the intended use. And at some point, we also said maybe we should really combine one and two and I think we had more work to do to really combine one and two. By the way, in the process of thinking about these things, we're also thinking about do we want a large number or a small number of litmus tests that can really demonstrate value because it's kind of hard to hold in your head a hundred different topics. Really, we kind of want to get to core principles

that -- that drive towards the end values that we care about. That -- the third one is like safety issues are systematically anticipated, monitored, managed, mitigated. Like, I think trying to have a -- like safety frame in -- in our processes is really critical, that the processes are well defined, followed, transparent, communicated, monitored, and continuously improved. Followed was an interesting word in here. You can have a great process, but if everybody in the team isn't embodying that process, it's not really that useful. We think that trying to get to where it's an intrinsic part of the process was a really important piece, that, you know, everybody on the team should know what the process is, not because they read it in the manual, not because the document is available, but because they're doing it every day and really, it should be emerging from how you build great products. One of things that also came out of all this discussion, we also like many of the other groups talked about large and small companies. We had the advantage that --

that Howard and I were there representing the smallest of the companies but we also had folks from Roche and J&J and Verily in the room, plus other large pharma companies that -- and other companies that were not part of the precert program. But we kind of took a really contrarian view that actually the smaller companies have a real advantage in this. They're able to build intrinsically into their systems much more deeply these kinds of principles and ultimately if we're not measuring something that has real efficacy value, we probably shouldn't be measuring it and if it does have real value in -- in the areas of patient’s safety and efficacy then we shouldn't be lowering the bar for small companies and I say that as a small company person. You (inaudible) that. So, I encourage the agency not to have a totally two speed approach. We think that if we care about rigor we should care about it equally. Maybe how you demonstrate it is different at a very large scale company. Obviously to the point somebody made earlier, if you're sitting across a

table from everybody in your team, communication methodology is not as -- doesn't need to be as elaborate. You should still talk about certain things. You should still have stakeholders present. But it's easier to do it in a small company than a larger company. We got a little hung up when we tried to get into how you measure this stuff. It got very -- not very far in looking at what are some KPIs we can clearly look at for this stuff. We tried to map them as much as possible to multiple of these sort of hallmarks of quality and I think that's a nice approach. We don't want a million metrics. We want a few metrics. Okay. And I will wrap …

MS. CRUZ: Thank you very much. Other group?

UNIDENTIFIED FEMALE: So we did kind of a bifurcated process. We talked about processes, so we spent half of the time -- half of the group spent their time rewriting the processes and the other half spent their time on the other exercise. And so, they might not perfectly match. But we talked a lot and I already emailed Marisa, so I'm

not going to read all of our new processes. But one of the conversations we had is that we need a process to make sure that processes are continuously improved, so like very meta but probably necessary. The other thing we had a lot of conversations about was users versus customers and where FDA should focus and a lot of our folks had some really strong feelings about whether or not FDA should care about their business relationships and their customers or about the, you know, public health and safety and the users, being a patient and provider, so we had a lot of conversations about that which was really interesting and let me turn it over to you to really do a read out of what we did.

UNIDENTIFIED MALE: Okay. So, yeah, our team was struck with the terminology as well, with customer and user, then safety and beneficial and something what you -- optimized. So we struck as we go to (inaudible) but as we agree on -- so the overall theme is the -- all the characteristic of the excellent touches or the excellent principle.

One interesting take is proactive culture, how people want to bring it integrated into more of a software development process. For example, like, software should kind of (inaudible) tech era and sell correct as well, so I thought that was an interesting take. And then as we looked through the KPI a lot of us want to kind of break down. For example, one person say that the process of delivering high quality may not deliver a safe product, so they want to break down the product quality and safety to measure that separately.

MS. CRUZ: Okay. Perfect. Any last takeaways? Do you guys feel like you covered the moderator perspective? Any questions for the group's focus on process? Okay. I know we're standing between you and lunch. So, we will break for lunch now. We'll regroup at 1:00 p.m. and dive right into break-out 2, focus and results and then work on wrapping it all up. Thank you.

(A break was taken.)

MS. CRUZ: Okay. Great. So, thank you everyone. So we're going to again structure this

slightly differently. We're going to have the groups that were focusing on customers go first. That's 1 -- Groups 1, 5 and 10. If the people doing the readouts could give a brief overview of the discussion, two to three high level takeaways or themes and then we'll cycle on to the next results category.

MR. KAPPE: All right. So we were dealing with …

MS. CRUZ: Sorry, for the purposes of the reporting, could you introduce yourself and your group before you speak?

MR. KAPPE: Okay. So, I'm Bernhard Kappe from Orthogonal and we were Group 10 dealing with customers. So, there were a couple of big scenes I think that came out and a couple of things that were -- caused lively debate. One of the things that was a -- a big emphasis that resonated was the concept of active monitoring, so really doing that throughout the life cycle, both qualitatively and quantitatively through the entire process. A second one was don't be fearful of the data. You

know, there are lots of different potential data sources, you know, from FDA, from the company, passive from the market, embrace all those -- that data and don't be fearful of it, use it. At the same time there were -- was a lively debate as to what is proprietary, what should we disclose, are we willing to disclose as far as data versus what we capture and use. That's something that really will need to be thought through carefully by the FDA and by all the participants. In some cases, there may be standards and benchmarks that we -- that we can leverage and use, but very often there -- some of those standards are just not there yet and they may need to be created, so thinking about benchmarking in the context of what are people willing to share. And then brand was an area where, you know, the traditional brand concepts may be more appropriate for larger companies versus earlier stage or startup companies and maybe there are some other measures that could substitute for brand. We certainly felt that this area touched on all of the main principles.

Another area we thought needed a little bit better or further clarification was around what do we mean by customers in this? We took the view of a, sort of, a larger -- larger scope, you know, users, people who pay for it and other stakeholders within this, but I think that -- you know, that term needs to be clarified a lot better in -- in the course of this.

MS. CRUZ: Great. Group 1 or 5?

MR. BERNSTEIN: Group 1, Danny Bernstein, metaMe Health. So, I think I can echo some of that. I think one of the things that was brought up was the -- whether the application here is thinking about pre or post market, what's the intention and perhaps some language that kind of backs up, gives more depth into -- to some of these characteristics, so we know how to think about them perhaps. Also, something that came up throughout was the difference between referring to these as products as opposed to a product, so perhaps a product for a company who's doing this for the first time versus products for the company

that is eventually putting out two and more products. The other piece for benchmark, I think part of it was to evaluate perhaps process the company takes towards quality, rather than some fixed standards. And so that's part of the culture. And -- and then the benchmarks also to match the company size and to recognize that KPIs might be iterated over time. On the example metrics there was some question as to whether brand reputation should be included and then also perhaps the collapsing outputs from human factor studies and usability testing results. And I think for the most part that's primarily it.

MS. CRUZ: Thank you.

MR. LOOK: I'm Howard Look, Tidepool. We're Group 5, also looking at indicators from a customer perspective. We got right into it and identified some interesting themes. One is there's a notion of a primary indicator that we think the FDA should be looking at and then there's a notion of a secondary indicator where we as a company might want to look at it, but we

actually don't think it's the FDA's business to look at the actual metric itself. And similarly, we thought brand reputation or your retention and engagement metrics, for example, it's not important that the FDA actually look at those things. If I want to call my app, makes you barf daily, that's my problem. But the fact that I'm tracking what the results of that brand are, we can say to the FDA, yes, we track that but what the actual outcome is, is our problem. So, there -- it's a notion of primary and secondary indicators. And then we also had a notion of leading indicators and trailing indicators. Leading indicators are things that we actually measure as we're developing before we deliver to customers. Trailing are things that you might do post market. And then we went through and came up with a bunch of ideas. So, obviously things like defect rates, adverse events, efficacy are all primary indicators, voice of the consumer being traced back to new product requirements would be a trailing indicator, but would also be primary

because we do think it's important for the FDA to look at. Customer understanding of risk and benefits, clearly expressing what the risk of your product is and making sure that the customer understands it would be something that is primary. Sorry, I have lots of great notes here on a big piece of paper. Consideration of customer impact in decision making, this was an interesting one. The example of your CEO comes in at the last minute and says, 'No, we should change that' and imposes a change going outside of your usual process. Measuring -- paying attention to what the impact of that on the customer are and noting that it was a deviation from your defined process and measuring when that happens and what the effect of that is. And then another theme as with the prior two groups was all about analyzing and reacting to data. We think this is probably the biggest thing and perhaps is worthy of being a sixth pillar, right? The notion that as software developers, we -- it should be incumbent on us to make sure that our software can gather data and it

should be from real customers and we're paying very close attention to data quality. And we're looking at the performance of our software and we're looking at raw data, not just cleansed down the -- downstream data. So, I think I covered everything.

MS. CRUZ: Thank you.

MR. LOOK: Oh, sorry, there's one more thing. We had -- we all had a universal reaction to the word customer and we don't think they should be called customers. They should be users or intended users.

MS. CRUZ: Okay. Let's move on to Groups 2 and 6 who were focused on business.

MR. KERR: Hello, I'm Matthew Kerr from Abbott and our group was looking at a series of business metrics, so we were given a list including things like market valuation and market share. Sorry. At a high level, our group generally believed that most of these business metrics were not that relevant for the FDA. If they were applicable they may be applicable in the post market

surveillance phase and they're of course only applicable to companies that have already launched a product and there's a history to evaluate. There was a bit greater enthusiasm for tracking things like consumer satisfaction, which goes back to the prior group's point. However, there was an area of the business metrics we believed was important and that was the supplier quality. We believe that it matters that if a company is contracting out some of their supplies, that the quality of those suppliers matters and so if there are contract disputes, if there are mistakes, whatever the metrics are around that, that those are meaningful and relevant to the FDA. Finally, as a third point, this is a subcategory of supplier in a way, but we recognize that cloud service providers are a particularly difficult issue. Intuitively, it doesn't seem to make sense for a whole bunch of companies to try to create that service on their own. There's a risk in the stakes there. On the flip side it could be very difficult for a company to go and audit or

evaluate some massive cloud service provider. So, we didn't have a clear answer, but we believe that's an important issue there should be clear guidance on.

MS. GEORGE: Elisabeth George with Philips. We're in Group 2. We had the same areas to evaluate. Yes, we're a very rowdy group back there. You notice we had to come up with two this time. So, like my colleague here, we too had some significant concerns. Actually, we put no to money on our sticky notes, so we didn't feel that those were areas to monitor from an FDA standpoint for precert because we felt it was really most important to focus on the product and the processes. With the second area of it we had discussion on was resource allocation. We felt it really should be adequacy of resources with the focus being on the ability to execute the activity as defined and we felt that was much more important than the -- than money element. Now I'm going to hand off to my partner in crime.

MS. CODER: 2.2, Megan Coder, Digital

Therapeutics Alliance. And for the second half of our group, reliability really underpinned all three of the things we added. So, looking at the four characteristics, we felt that the first two in financial resource probably not. The second two are good. But then adding the third, the entire supply chain must have this highest level of quality across the board. Next one, business continuity, there has to be consistency and strength in your employee base. Losing one loses -- who's really important, integral to your processes could really affect your organization, losing more that could even have greater impact. And then we talked about having a customer preference process, not just knowing what customer complaints are on the regulatory side or knowing what their likes are on the marketing side. But really what is a proactive way to understand the preferences of your customers.

MS. CRUZ: Thank you very much. Moving on to society and public health, Groups 3, 7 and 9.

MS. MODARES: So Group 3, thank you all for

your comments. We identified …

MS. CRUZ: Introduce yourself, Roxane.

MS. MODARES: Roxane Modares, FDA and John Murray was also my co-moderator, FDA. So, we identified a few top five for our public health and society, access -- access to the devices, updating the software, it should be continuous. There should be no hold up, so improving that speed to updating. Cyber security, they identified was also essential. Something I thought that stood out that was really great was how -- how easily can you share this information, the digital health data that we have, what is the capability in -- in the clinical use. So, you have a lot of data. Can you make it applicable and appropriate for clinical use, doesn't necessarily have to, I guess, just be clinical. But an appropriate format and there was a lot of discussion between satisfaction -- customer satisfaction versus the patient safety and efficacy. So being able to improve both of them at the same time and not just choosing one or the

other, different concepts there. And let's see here. Yeah, so back to assurance of access, one of the members identified that that should be another characteristic that has not been included in our characteristics list, yes. John?

MR. MURRAY: I'm good.

MS. MODARES: All right, I think that's it.

MS. GURNEY: All right. Laila Gurney, GE Healthcare from Group 7 here. So, one of the things we struggled with was actually the -- the way that this was put together with society and public health actually. And while these characteristics we felt are super important for a great organization and an organization everybody wants to work for, et cetera, some of this, same with some of the business characteristics that were named earlier, we felt didn't quite squarely fall under what perhaps FDA should look at from a precertified organization. Although the metrics that are explained here, some of them do tie out to some of the enablers that -- that we talked about before such as impact on health outcomes,

for example or, you know, perhaps if we want to look at patient safety more closely here as a characteristic or a group versus like society. Some of these characteristics could perhaps be worded a little bit differently or maybe more specific because they're so broad, they could -- they could -- easily you could fit anything under them. And they would apply across the board along the excellence principles, but they are a little too broad to be able to put our arms around it, so some of these could be made a little bit more specific and perhaps a little bit more applicable to those various enablers.

MS. CRUZ: And I think we have Group 9?

MS. SHRADER: Pat Shrader, Hogan Lovells. Group 9 was stunningly quiet and I was thinking that it was because it was after lunch, but now that I hear everyone else talking a lot, I don't know, nap time. But I thought at the time that perhaps what it was is that the group saw a lot of good alignment between society and public health and the excellence principles. There wasn't a lot

of discussion around that. We did talk as we had talked earlier about the challenges of defining the characteristics that would be expected of an excellent and outstanding company that had no product on the market versus a company that had product on -- or multiple products on the market. So, are you looking for -- are you actually able to look for performance or do you really need to look for good plans if you're talking about a company that's venture funded and -- and pre-market. The -- we had the most robust conversation around customer feedback and our first comment, which I've heard here already, is well, you won't -- if you're looking at society and public health, you're looking at a lot more stakeholders than just customers. Certainly, you always are interested in hearing from customers, but there are many other components in a healthcare system that you would want to hear from as well. We also talked a bit about what it meant to be integrated into a healthcare delivery system. Were we looking for, you know, percentage

of adoption of a -- of new technology? Were we really being product focused or did we really need to be more company focused? Were we looking at accessibility or were we looking at time to adoption or ease of fitting something into existing workflow such that a new technology would not be disruptive? We also talked about how do you measure things like social responsibility and sustainability and there are of course third parties that do that and there are companies that participate in those annual assessments that are done by third parties, so that's something that could be considered, not necessarily whether -- whether the company got ranked, but whether the company was interested in understanding whether it ranked and if so where. So, we also talked a bit about some -- some of the metrics I think require a lot more definition because it wasn't really clear how you would measure in certain things like user retention. And somebody brought up the fact that, you know, if you're developing software for a hospital system but you're part of that system,

user retention isn't a very meaningful metric because users may in fact actually have no choice. So, I think there -- there was a lot of great discussion, there's a lot of energy around figuring out how to measure the impact on society and public health and there's a lot of opportunity here to better define those things.

MS. CRUZ: Thank you very much. And our last group was focused on people and that was Groups 4 and 8.

MR. MCCRAY: (Off microphone.)

MS. CRUZ: Just press your button.

MR. MCCRAY: Rob McCray, Wireless-Life Sciences Alliance. And we have a big and diverse group and I'll use 'we.' It's hard to get a consensus within 45 minutes on a topic as big as this. I think, sort of, the grounding principles for our discussions, the two today have been think about a system that scales from very small companies to very large companies. And one of the questions that sort of continues to come up that we run into in both discussions so far is to what

extent should it -- should it also be scaled to the -- the product, the humanity risk or value of the product. So I'll just set that aside. The people -- the examples here, there were 13 examples. We did not examine those one by one. I think there was a general consensus that depending on the size of the company and the nature of the product, all of those example metrics are very good and important to the company and I suppose to its stakeholders. But the concern is how much should FDA -- how much does FDA have to examine them itself and maybe underlying that is a concern of how to avoid a process that ends up being more burdensome than rather than less burdensome which is certainly the goal. So when you boil it down, there was absolute agreement that talent is critical, having the right talent in any -- a company of any size for a medical product is critical and that's hard to judge. A big company can have great talent but not the right talent for a product. A small company may have little talent generally but has just the right talent for them

to start a product. So -- but that is critical and getting at that and somehow measuring it is important. Secondly, that culture is critical, culture equality from the leadership down through the organization is critical. And -- but again the concern is how do you deliver that. One suggestion is more in the way of a report, the HIPAA model, I'd say the public company, SEC model of reporting a public report on what -- on these factors, on how you manage these, how relevant they are to your specific concerns, your specific product and -- and stage of life cycle for the company is one approach. A survey approach or looking for indications -- objective indications from employees within an organization as to whether they feel they are supported in creating quality products is another suggestion out there and -- and there are certainly commercially available ways to -- to deliver those metrics. So let me just compare -- yeah, I think that's -- that's kind of as far as we could get in the time available, thank you.

MS. CRUZ: Great. And Group 8?

MR. REID: Hello, we're with Group 8 and I'm Keith Reid from KJR Limited. And my colleague here is?

DR. GOTTLIEB: Oh, I'm Samantha Gottlieb. I'm a Medical Anthropologist.

MR. REID: And our first takeaway point seems to be a common theme of why does the FDA care. So maybe that's the wrong forum for that. Anyway. So some of the -- if we look at some of the example metrics, we've got average vacancy duration, offer acceptance rate, social media ratings, employee participation as brand ambassadors and brand reputation. We didn't think that they necessarily tied back to drivers of excellence. There seemed to be too many other possible influences on those particular metrics. That was the first point.

DR. GOTTLIEB: Yeah. And sort of related that these -- KPIs, are these really controllable and certainly things like social media and sort of brand ambassadorship seem to be sort of highly --

potentially very fluctuating and, you know, how do we really capture that. And -- and I think Marisa pointed out, you know, sort of the possibility of looking at variability over time as sort of one strategy, but it still struck us as sort of a problematic, very sensitive kind of -- sensitive in the sense responsive to, sort of, factors beyond the company's control. And then sort of to lead it back to this question of sort of trust that pre-certification is trying to achieve, how does this really, you know, capture that -- how is that important to evaluating whether that trust is actually in place, whether the company is representing, sort of, what it's setting out to do. And then we had sort of a final point, I guess -- of the sort of, you know, thinking about this, I think maybe -- some of us was talking about this kind of question of, you know -- I mean, it was Howard talking about the sort of outcomes rather than actual measurements and so in these kind of evaluations, is it really that critical to look down at this kind of granularity

or is it more important for the companies to sort of state, yes, we have a process and have that clearly detailed but not requiring there to be some kind of standardization because as everyone keeps mentioning and pointing out that, you know, company size, structure, all of these things are highly, highly variable and -- and prescription is not constructive, but that there's sort of a clear commitment and that's part -- and highly well laid out but that's allowed the variability that's intrinsic to the -- to companies.

MS. CRUZ: Okay. Thank you everyone. Let's give a round of applause to everyone who came up. So if you could just remain for one second. Thank you. So we do have about five to ten minutes. Are there questions for our panelists/break-out group representatives?

DR. MCMAHON: Yeah, this is Chantal McMahon, Medtronic Diabetes, Data and Digital Information. Elisabeth, actually first question's for you. I was also part of Group 2. One of the statements that you had made was about resource allocation.

And the way that I had interpreted that statement was actually more along the lines of resource allocative toward innovative products and processes. And so, I think that's an important kind of distinction to make because maybe the resource allocation makes us a little bit antsy. But really the idea is when you're defining a company for their excellence, how can you evaluate the amount being innovative? And I think it's a really interesting concept to talk about, so maybe we can delve a little bit further into, you know …

MS. GEORGE: Sure. The group did talk about that a little bit. And -- and one of the things that we felt was, was again, we didn't feel that that was something that the FDA needed to necessarily know exactly what our percentage of resources are specific to innovation because to be honest with you, I know many public companies actually have to say what percentage of -- is in R&D and there -- there's a lot of those things already. And -- and what's innovation to me may not be innovation to you and so there was some of

that discussion. So it was really -- the focus that the team kind of was going for was is that do we have the right resources to target the things that we feel are important as the business that we're targeting for the precert. So, those resources may be regulatory resources. They may be clinical and they would not normally be captured in the R & D innovation calculation that many companies would do. So that was kind of why we shifted it a little more to the -- to a more general focus as to what the intended purpose of the focus of the area was.

MR. PATEL: (Off microphone.)

UNIDENTIFIED FEMALE: Bakul, you're not supposed to ask any more questions.

MR. PATEL: I'm going to be a laser here. So Sylvia, go.

MS. CRUZ: Go ahead.

MS. TRUJILLO: Great. Thanks. I was really fascinated by the suggestion for another pillar around data capture (inaudible) and my both question and request would be to mop out that

pillar because I think it beautifully captures, I think, ongoing concerns you heard about what -- why does the FDA care, why do other people care when really we're looking at outcomes and immediate feedback loops on the outcomes from the users, not just the intended users but actual users, I will say and it also speaks to if you build it in advance, that would be relevant for premarket and then post market. It would tell you about performance over time and I think that's something we would really urge that group and I would like to volunteer to -- to collaborate with you all to more fully vet that out. Thank you.

MR. LOOK: Can I make an editorial comment on that? So, this is now me speaking. It wasn't my group's consensus. Access to data both from devices and -- oh, sorry, access to data, both from devices and software, I think is a key tenet not just of software but of devices. I might argue that if a company says, 'We agree to make all of our raw data available to the community, to the users as well,' they should jump straight to

the head of the line of the precert program and be able to ship right away.

MS. CRUZ: Thank you, Howard.

MS. BLEICHER: So I had a more a global question. I'm Esther Bleicher, I'm from FDA. In our group we -- the participants struggled with really the concept of -- not the concept but the actual results categories, we had -- and it was echoed really across the panel, why does FDA care? Is this really in FDA's purview? And so my question to you is whether you think that these results categories could be narrower or refined so that they could be appropriate and useful for facilitating precertification or do you think we should just chuck out and try something else as we iterate on this process?

UNIDENTIFIED MALE: I have an opinion. I don't think you should chuck the whole thing. But I do think there are components. Like the brand part, like, let companies choose their brand and, yes, it's important for a company to understand how their brand is being perceived and that's all

part of building a business. But, no, I don't think that should be part of the regulatory precertification program. Safety measures, defect rates, adverse events, efficacy, incorporating voice of the consumer back in the product, absolutely, all of those things, those are direct measures that are legit for the FDA to look at.

MR. PATEL: So I'm going to carry where some of you left off and Esther left off. This is Bakul Patel. I'm going to ask the panel to think -- just view two perspectives to think about and I know there was a lot of focus on 'does the FDA need it or not need it?' I think, as you guys all heard me talk a couple times already, what would you think -- how would you think about those metrics when you're recognizing either your supplier or you're recognizing -- or you're trying to figure out if a company is excellent, you're talking to your peers. So if you think about it from that perspective, how would you look at those things as opposed to whether FDA needs it or not? I mean, this whole point about this exercise was

does a business need it to show excellence and it's less about does FDA need it to show excellence. So I think we can -- we can determine after the fact how much FDA needs and how much it does not need. But the question I want to put out on the table is, like (inaudible) understands that we all think FDA does not need or need, are we leaving some part of recognition that you guys care about very deeply as businesses to -- to be included as part of the concept of giving recognition of what you -- what you sort of think very highly of how you run your business, so I'll leave it at that and see what the panel …

MS. GEORGE: This is Elisabeth George. I was just going to pick up on one of the things that you said earlier was, is there metrics that I think are important for this program and then there are metrics that we do as companies? We do thousands of metrics at Philips that are important to us, that are important to our stakeholders that may be important to specific customers, but I don't feel that they're all important for the FDA

or for any regulator to see. And I think that that's what's going to be important with what we come out with from today and the subsequent activities is, is that, you know, as a company we're going to measure things that are important to us, that are important to other people, but we should keep any amount of metrics that are used for any activity of certification to -- you know, we want to call them key performance indicators which usually means a small, few, not thousands. As a company we do thousands, but I'm not going to show all of them to everybody. They all have their place and time.

UNIDENTIFIED MALE: I -- if I can jump in? I'd say the -- for the people characteristics or metrics, having the right talent to create and support the product and having a corporate culture of quality that supports the continuation of quality in that product and its improvement following the evidence would be the lowest common denominators. All of the other factors by and large are taken care of by the much larger market

in which all of these companies operate, especially as they reach scale because they cannot survive unless they have most of those characteristics internally delivered in different ways. Speaking as an individual I would say the best sign of quality -- best kind of signboard to quality or lack of it is actually in the product's performance in -- in the hands of the end users in the real world, so -- but that's me personally.

MR. BERNSTEIN: Danny Bernstein. So, basically speaking to Bernhard and Howard's comments about active monitoring and the data, it feels as though the FDA does have a responsibility for public safety and therefore the data that goes back, that's one level of importance and then the ability to communicate out to the patients/customers is of prime importance. If -- if an update to a software platform is going to break something, then perhaps the message is 'don't update until so and so' or if something's gone wrong or something you realized then that can be communicated. So, the opportunity in today's

day and age is to create a full cycle loop, not only for the customer or patient -- patient-reported outcomes, but the customer satisfaction as well as the product's performance. Thank you.

MS. CRUZ: Okay. So we're just about out of time and we have two additional questions. So I'm going to move on. What's your question, sir?

MR. BURCH: Yeah. My name is John Burch. I'm with Angel Capital Association and I have a comment and a question about the data. One of the panelists said that don't be fearful of the data. I would disagree respectfully. I may be incompletely different context here but do be fearful of the data. The gorilla in the room is the electronic medical record. All electronic medical records have significant mistakes in them. One-third of those are by statistics (inaudible) catastrophic if they were actually used in some sort of a, you know, mechanical way. I think that this whole industry -- this emergent industry that we're part of here will find a -- that it's hitting a barrier because of the -- because of

that call, because the data that it's going to be working on, if you're going to scale in dealing with a market of hundreds of millions of patients, which is certainly what we hope, the data just isn't there and we don't really even have good mechanisms in place today to do something about that data. I think -- I'll finally just comment there's two general categories to be talking about. One is the data that -- that your software will operate on. That's what I'm talking about, but in addition to that, there's the data that is used to perform -- to evaluate your software, how well it is doing. And that's the business really of the NEST project, as I understand it, to be really looking at that. But it's -- we have to be thinking of that as well and making sure that both categories of data are reliable. And I just think although we're moving toward -- inevitably in my view toward patient center data repositories, I think that's going to happen one -- one form or another. And I think that would clear up the data. I still think we have a major problem here,

unless we can do -- really address major -- major issues having to do with -- with healthcare data.

MS. CRUZ: Thank you. One response?

UNIDENTIFIED MALE: So I don't disagree with what you're saying. I think maybe rephrasing it, have a healthy respect for the data and the problems and -- and issues of quality of data. But don't be afraid to engage with the data and collect more data and use that data appropriately.

MS. CRUZ: And Seth?

DR. CARMODY: Seth Carmody, FDA. I have my very own question I thought of. Can you believe it? Thank you. Thank you. A question towards Elisabeth. We work together in the cyber security realm and folks from your organization. I'm just curious. Is there some parallels we can apply to what we've done in the cyber world to this world? You mentioned there are just some things that FDA doesn't need to know, right? We've tried to engage on cyber security, like, on vulnerabilities, like trying to get people to talk about the things they don't want to talk about.

So I think it's really important for us to tease out why you don't want to share some things with the FDA. I'm interested in a larger conversation. I don't think it's going to happen here. But is it because you're afraid of punitive action that we'll take something that doesn't really pertain or is germane or jurisdictional to the FDA and then take some punitive action? Is that the primary concern or is there other things that you're worried about?

MS. GEORGE: No, not at all. I think specifically when we're talking of finance, having spent almost 15 years of participating in FDA advisory panels or in any discussions, whenever an industry person started talking about the economics, we were slapped and reminded, 'We don't talk finances, we talk safety, we talk results,' things like that. So, that was really what that whole premise was about, about why we don't feel it's necessary to share. It's not that I'm saying it shouldn't be shared. It shouldn't necessarily be the number one criteria of how we get through

precert. I do think that transparency, we've talked about this openness is appropriate and you're right, in the cyber security world as far as I'm concerned, you know, the emperor with no clothes, that's what it should be. I mean, we should be willing to be open and honest and share and share not only with us to you but us to the whole room. So I agree with that.

MS. CRUZ: Thank you. So we're out of time. Is it a very brief question?

UNIDENTIFIED FEMALE: It's maybe more of a comment than a question. But it's --

MS. CRUZ: Okay.

UNIDENTIFIED FEMALE: -- germane to what we were talking about. So I had the same kind of reaction to this (inaudible). I think it's less about what we want the FDA to see and it's more about whether it's germane to the conversation, right? This is about making sure products -- companies that make those products should be sending those products out to the market and whether they're controlling them properly. If

they're controlling their finances properly, that's a different question for a different set of people. So I think the reason you're getting this kind of (inaudible) rejection -- rejection and reaction is that it just doesn't seem germane to what we should be looking at. It just seems like those should be separate, regardless of who sees what. That's a different question. It's whether it's relevant. I think that's -- for a lot of people that we were talking to.

MS. CRUZ: Okay. Thank you. Thank you everyone. Okay. So I think the last break-out session is going to dovetail very nicely with what we just talked about, right? So, there's a question of what are the safety and -- safety effectiveness results that FDA has historically looked at, what -- what kinds of results should they be looking at for a precertification program. There's a question about whether measures that we've not traditionally looked at could be proxies for other activities and processes that excellent organizations have in place. And so we asked. We

went on the site visits and we asked the pilot participants and other stakeholders in the digital health industry, what's important to you, what would you show FDA if you were going to send in a scorecard or a dashboard or some sort of tool to help you aggregate disparate data elements and -- and help FDA to make sense of them to give them a sense that you are an excellent organization. So, that's going to be the focus of this third break-out session. You will be provided with a packet of example scorecards, again drawn from a variety of stakeholders as examples of tools that could be used for this purpose of aggregation and scoring. The purpose of the break-out sessions is not to review the scorecards in great detail, but to use them as a reference points and jumping off points for the discussion. Each break-out group has been asked to solve a problem statement relating to a dimension of data aggregation and scoring. And so those are broken down here. The groups are going to be asked to discuss mapping and aggregation, weighting and minimum thresholds, reducing

regulatory burden, considering tiers for precert and the bounds of precertification. So, if you can divide again into your groups? We'll -- we'll regroup here at 3:15.

(A break was taken.)

MS. CRUZ: So I think we're going to go ahead and get started. Since you were so prompt, 5 and 10 get to go first. So for this readout I'd like each of the pairs of groups to tee up their problem statement, just explain a little bit about what your exercise was and then give a few key -- key takeaways.

MS. DEGRAFF: Okay. My name is Jill DeGraff. Our problem statement was really to consider the characteristics of the minimally viable candidate for the precert program if you will. And as we were developing our thoughts on what those characteristics might be, we were mindful of three principle goals for the precert program. Number one is to spur innovation. Number two is to alleviate the regulatory review burden for the FDA in anticipation of a flood of applications. And

then third to, of course, maintain and -- and accelerate overall product quality in the market place for these products. So we -- we first started with the Post-it exercise of trying to identify a number of inclusion criteria and exclusion criteria for lack of a better word, which we really thought of as red flags and you know, the -- the idea that really seemed to -- that we end up collecting this inclusion criteria around ultimately turned on the idea of a -- of a precertification application process. And that that process would look a lot like what the -- the 510(k) process would be so that if you're already going to do the hard work of a -- of a 510(k) and we're not planning to, you know, lower our standards at all, then you should at least be able to complete what you would otherwise complete in a full 510(k) in your -- in a pre-app for the program so that when the FDA is looking at you, you would -- you know, they could come back and say you're not ready based on whatever those criteria might be. But then at least you go

through the 510(k) process and then you get known by the FDA. But as we were thinking through the inclusion criteria, we were really mindful that, you know, there are a number of different personas that we're really going to need to develop, that we didn't have time really to do, but we want to think about the kind of candidates that we would want to see come forward. It wouldn't be appropriate, for example, in the view of our group to set minimum, you know, funding caps or levels or, you know, that you're -- an organization is beyond the development stage or that it already have a product on the market necessarily, if you can otherwise demonstrate through the precert app that you already have the experience and have put the hard work in to develop and implement those principles of excellence. Do you want to say anything?

UNIDENTIFIED MALE: Yeah, in that spirit, I think one of the things that -- it seems really clear that the FDA wants us to be a big tent policy, so the idea of not filtering people out

prematurely was -- was clear in the intent. But we also recognize that it's going to -- there's going to -- if there's big amount of demand, you don't want it to become burdensome to the agency either. So we kind of thought about this idea of having this pre-filter process, the equivalent of almost a self-administered quiz or something like that, that starts to frame what you have to do to be able to pass the precertification program that you could do on the input side, almost as a -- as community education tool, but also something that would help them to produce some artifacts that could be more readily filtered to say, 'Oh, this -- these people seem like they're pretty close, we should talk to them. These people seem like they're pretty far off, maybe we should send them this white paper that explains why quality matters,' that kind of thing, so …

MS. MYERS: Okay. We -- I was part of Group 10. My name's Nancy Myers with Catalyst Healthcare Consulting. We -- our focus was the bounds of the precertification and what

constituted a minimum threshold for an organization to be eligible to submit to be part of this. And we -- we did not use Post-it notes, I'll tell you that. We really focused on -- I think, strength of our group was asking questions. So, I think -- every time we came up, 'What about this, what about this? So I'll now give you a list of our questions, which gives FDA more homework, but that's what I love to do. So we -- basically we had a conversation about should there be levels of precertification. We talked about a possible star rating, how do you -- both big and small -- we didn't think the concept of big and small mattered, but perhaps experience might matter. And so we -- when we talked about a possible star situation, we had a really interesting comment from someone who said, 'Hey, listen, I'm with a big company and we're new in this space and we do not want a bronze star. We are always going for gold' and we have -- 'we're very good at putting processes in place and so we shouldn't be --' so, I think as we talk about

possible -- creating possible levels of precertification, we ought to look at what the optics are. And also -- we also talked about the possibility of a driver's license situation. Somebody else was talking about it, but my oldest daughter is about to get her license. It scares me to no end. But, you know, would you have a -- would there be certain standards where you kind of up, you know, your -- if you're precertified as a -- as a new -- a new entity, maybe you have to do four other things to prove that you're ready, especially if you don't have the data already and don't have an approved product already. Another question that we talked about was -- we talked about precertification, is all of this asking too much. The goal of this is to encourage people to use this process. You -- it's bringing -- it's taking the 510(k) and raising it up. But as you're asking the questions, that's just something -- just to keep sure -- making sure that it isn't so onerous as FDA is creating its dashboard that nobody wants to go through it. And then it was

also -- one question in -- in that kind of -- you know, is this something that if you have a high-risk device that is only doing minimal modifications, are you -- could you go through the precert process? That hasn't really been talked about. Then we also talked about -- if you're looking about the bounds of precertification, do you get a precertification for your whole company or just the part of your company that's doing software or if you have that, are you -- is it just the group that's leveraging the quality system that's pre-certified? That was a big question. Are you leveraging -- let's see, what else did we ask? We asked, is there a different process if you've got a different intended user, if you're only focused on doctors or patients, you know, where does the precertification come there. We also talked about how long are you precertified for. Is it something where you're precertified in perpetuity and I don't think anybody encouraged that. But is this something -- would it line up with your usual inspections, how would -- how long

would it last? Then, is it transferable? So your company that buys a company that's been precertified, do you get that precertification or not. And we also -- people were talking about -- we asked the question of how many people would be precertified and is that something that FDA could handle and is that threshold -- does that threshold change for your first set, you know, you're doing your pilot, but -- you know, some of those questions. And then let's see what else. I think that -- that was -- we had a couple more questions, but I'll leave it at that. It's enough work for you guys.

MS. CRUZ: Thank you very much. All right, do we have Group 7? Yes, okay. So, Groups 2 and 7 were weighting and minimum thresholds.

MR. NARDONE: Thank you. Jake Nardone, Dexcom. So, our group was actually really engaged, it was great.

MS. CRUZ: Could you just introduce yourself and tee up your problem statement?

MR. NARDONE: Yeah. So Jake Nardone, Dexcom.

The question was basically minimum thresholds for scoring. So, we discussed a lot of different scoring proposals and I think that we kind of all agreed within the group that from a product quality and patient safety perspective that the weighting towards those should be more significant within the scoring framework, whether it's stars or points allocation we thought that those should be -- basically have higher minimum thresholds. We also discussed establishing the minimal thresholds for each criteria, which would be evaluated for each organization. And one of the topics that was discussed was that -- the importance of having clear criteria for FDA and FDA staff to review and also hold each organization to the same standard and have that be clearly disseminated to the industry so that we're all aware of how each company will be assessed and held to the same modality. It was also discussed about whether or not there should be different tiers of excellence. And it was kind of leading in the way that it might be difficult for

consumers to understand a bronze versus a gold excellence badge. So, I think that threshold, once met, we agreed it would be good if it was just -- you reach a certificate of excellence and to that effect it might be beneficial for scores to be publicly produced in some website or manner of fashion for interested consumers or parties to be able to see how they stack against the competition. It was also raised that the -- the meaning behind the score could be a huge concern for industry as well as could discourage participation, based on what that is used for and how FDA intends to use the KPIs to monitor excellence. So, for instance, if we are looking at crashes or, you know, bug fixes relative and we see a spike within any organization's performance that -- it could be an anomaly within their system. They may have the appropriate procedures in place and that might not be a true indication of how they're performing. And one concern could be that that could lead to another form of punitive correction -- action from FDA or

potentially penalized by either removing that excellent certificate, so having clear understanding about how that would be utilized would be extremely beneficial for industry and I think it should be looked at cautiously so that we do not discourage participation from elsewhere in the industry. I think that's everything.

MS. CRUZ: Thank you. Group 2.

MS. JUMP: My name's Michelle Jump and I'm from Stryker. We're from Group 2 and we had the same question on weighting and minimum thresholds. We had a pretty spirited conversation over there, go Group 2, about this issue. And, you know, before we could even get into any kind of ranking, we got into terminology, right? How do you define these excellence principles? What do they mean? They meant different things to different people, which -- which I think is not uncommon, but it really became critical into understanding how you might rank them. I'd say the patient safety and the product quality certainly bubbled up to the top of our list as well. But we kind of quickly

moved into a space of well, it might depend on the organization as well. So maybe the ranking and the weight is actually the organization's determination and they make that structure and case depending on their culture and their products versus that being presupposed on the organization coming in. It depends on what -- what -- they may have been in a different field. They may have a structure that doesn't quite fit the same kind of weighting structure. So, we had some really interesting conversations around that and a lot of it depended, like I said, on terminology and how we're defining things like clinical responsibility and proactive culture. And then when we started to talk about minimum thresholds, we got to the point of -- it's really difficult to set those kinds of minimum thresholds when you don't have the actual criteria themselves, right? Depending on how the criteria are written, it would be very difficult. But since this is supposed to be something to demonstrate excellence, not something that everyone must comply to, it's voluntary. We

kind of cycled back to putting the onus on the manufacturer or the -- the developer. As much as I walked in here -- I'll just talk from my own personal point of view. As much as I walked in here going it must be objective, the more we talked in our session today it became more clear, I thought a lot about assurance cases and the fact that you provide evidence and link that evidence to your claim, that you're doing what you need to do and that structure can look very different for very different organizations. So we -- we kind of -- we ended that we need more information and that this really would depend on the organization. And -- and so having some flexibility there would be important.

MR. KESSLER: Gordon Kessler from AiCure. Also in this group, just to give some background on this, a lot of the questions that came up were about, you know, if you have a company that has 70 subsidiaries and they do all different things, what -- what does precertification mean, to whom does it apply, to which groups. What if you have

a subsidiary that keeps track of information in an EMR? So patient safety maybe's not really important at that point because if you're just (inaudible) a small piece of information. But cyber security might be outsized because you're giving a pipe into someone's main computer system in a hospital system, right? And so that idea of -- even if you pick a minimum threshold, I mean how low would the minimum threshold be? Just having someone on staff to recognize that that -- if that ever comes up as an issue in the future you need to do something with it. And so we also -- looking at that minimum threshold, we also talked a little bit about the other side of the coin, which is very small companies. If this is onerous enough -- and people have one or two products they might just say, 'I'll just do the 510(k),' right? Because the point of this, it appears, is to get companies along the path so that when they then apply for each individual product, there's a whole bunch of things that FDA doesn't have to look at again because they've

already been certified to this thing. And, you know, for companies it's supposed to be an efficiency situation and you're properly -- granted if it's going to take more work and very -- few times through the system, it may not end up being something that's sort of worthwhile to do that. And so we thought that while the idea of minimum threshold is a great -- is really interesting, we did -- as we said, you know, come up with the idea that it really maybe something that the individual organizations need to define what their weighting system -- what their systems are and then justify that to the FDA. 'Here is why we chose this. Here is why we did these things.' And also, a definition of what would perhaps justify the need to submit and request a recertification, right? We didn't have anything that was cyber security, right? We have a device that collects a bunch of information, doesn't transmit it and when you bring it back to your service provider, the data gets downloaded in a secure place. Well, all of a sudden if you add in

a Bluetooth connection or you add in a cellular connection that's real time, okay, no, the whole equation may change, right? And so how do you -- what do you do with that as the product -- it's not supposed to be product specific, but it has to be product related because someone doesn't need a large cyber security program if they have nothing to protect, nothing -- no risk on the cyber security side. And so, those requirements of threshold and when they should change, when people need to get recertified are something that I think really are unfortunately weighing against the kind of the uniformity and the objectivity of coming in and saying, 'Here's a checklist, once you fill this out, you're done.' And so that's really where we came out. And unfortunately, it's something that looks like we would think would be somewhat of a subjective determination of what's going on, input from the customer and -- and not a check -- not an ultimate single checklist.

MS. CRUZ: Thank you. Okay, we'll pivot to Groups 3 and 8, reducing regulatory burden. Group

3?

MS. ANTHONY: Agata Anthony from GE.

MR. ROGERS: And Bob Rogers from (inaudible).

MS. ANTHONY: So we were looking at reducing regulatory burden in the context of the metrics that the companies might or might not be collecting today and whether looking at those in the context of the precert program would make it easier without adding anything to the existing workload. So with regards to some of the KPIs that's the case, the most well populated metrics appear to be around product quality and patient safety. Those are collected and looked at pretty universally. Now, when it comes to things like proactive culture, we were kind of struggling to understand what that was really. So if we can't really define it all that well at this point, it's very difficult to put metrics around it and -- and look at it in a -- in a qualitative fashion. So, this is something that -- that I think would require further discussion. We were kind of wondering where that regulatory burden would get

reduced. So the conversation we had briefly was around what would get taken away. So we could -- we could look at those KPIs, use some of the metrics that are being used today and report those with some frequency. Annually we agreed wasn't -- wasn't often enough. Let's say quarterly or whatever the case might be. We were wondering what the mechanism for that would be. Would those be reports that a developer would send over to the FDA. If so, who would look at them? Would it -- would that be a time lag? What criteria would be applied to -- to evaluating this? So, that was kind of something we discussed. And what would not have to be done because we're doing this in the context of reducing regulatory burden. So -- so this is I think something that would require further discussion. We also concluded that things like cyber security and clinical responsibility metrics exist but they're perhaps not as well defined and as consistent as in the patient safety and product quality areas, so that would be a little more difficult to streamline and might

require some additional definition.

UNIDENTIFIED MALE: Yeah, I have nothing else to add. That was great.

MS. ANTHONY: Thank you.

MS. CRUZ: Perfect. Team 3?

MS. STEPHEN: Hi, I'm from Group 3. My name is Beth Stephen. I'm with Medtronic. So we also were talking about reducing regulatory burden. One of the first, sort of, topics we discussed actually was as far as whether reducing regulatory burden with the FDA would actually reduce -- how much it would actually reduce regulatory burden if we still had other, like, ISO requirements that we had the meet and, you know, requirements for EU or whatever. So, you know, if -- so, one of the questions that came up was, you know, it would help to just align requirements right across, you know, with -- if the FDA even just accepted the basic requirements, that would -- that would at least be helpful for trying to reduce the burden. You know, and then is the ISO standard good enough, is that something that people would want

to use or would they rather have it replaced with, you know, some new standard or, you know, whatever -- whatever the requirement might be? And then we -- we talked about the scorecards and using the scorecard as a way to improve on areas of weakness in the company, we definitely talked a lot about what the scorecard should and shouldn't do, who it was for. For example, you know, who was going to be seeing the scorecard, would it be just the FDA, would it be end users, would it be physicians? In that sense how much detail would be needed, you know, would they all get the same amount of information from the scorecard or would the FDA see everything and then maybe, you know, just some (inaudible) information would be available more publicly. What should be included in the scorecard and how the scorecard should be -- you know, how the scorecard should be arranged? Should it be just tiers or should it be like, you know, numeric values, what the level of detail was. Sorry, I'm just trying to read whatever the comments were. So, there just seemed to be a lot

more on the scorecard that sort of still had to be worked out. And I think that was the theme that came up with us kind of throughout this, was there was a lot more -- there's a lot more that needed to be talked about in this area and that, you know, we kind of needed more time than -- than we had to discuss it. The other thing that we talked about was the -- was excellence principles. We were asked whether the data, what -- which excellence principles we collected the most data and the least data. And for the most data, it was definitely the first three, the product quality and clinical and the patient safety. And then for the least amount of data collected, it was the proactive culture which was the very least and then cyber security after that. One of the things that -- that came up with that was that those -- that's how much -- that's where we collect the most and least data, but the -- the question is why is that the case because -- you know, so I think it's just a little bit more than just where do we collect more and where do we collect less,

right? Because one of our moderators said, 'Oh, so this -- these are the areas where you need to collect more data, right? The ones you're collecting less date in,' and I was like, 'Wait, hold on a second, that doesn't mean we need to collect more data. That just means, you know, in some -- in some cases you don't need that much data in those areas' and it will be variable based on the, you know, company and device and whatnot. And in some of those other areas where we collect the most data, why do we collect that data and some of it is for internal use and some of it is for reporting, right, to the FDA or other regulator. So just asking the question of how -- of how much data we collect is sort of not the full picture there, I think.

MS. CRUZ: Thank you. I'll move on to Groups 1 and 6, mapping and aggregation.

MR. ARBITER: I'm from Group 6. I'm happy to start. My name is Brandon. I'm from Tidepool. And under mapping and aggregation we were asked, how should FDA aggregate KPI scores across

excellent principles. And we were given an example of nine KPI for a single excellence principle and asked how would we aggravate them to determine an overall assessment of safety? And we basically said no. Some of the KPIs were yes, no questions. Some were percentages. Some were ratios. There's like -- these aren't -- these can't be aggregated. But we spent some time thinking -- thinking through that, talking about why that is because ideally it would be really cool if we could get one kind of FICO score that determines you're in or you're out. But it seems like one of the intentions of this program is to not be too prescriptive of companies. And an easy way to make it easy to aggregate is to give everybody the same exact KPI and say, 'Here are the KPI you have to measure and track.' But if we want to not make it prescriptive and let companies define their own KPI, then the FDA figuring out a weighting system to address each individual company's KPI would seem to be overly burdensome and not realistic. Maybe in five to ten years

after collecting a bunch of KPI from many different companies across industries, FDA could re-evaluate whether there is a more prescriptive approach they want to take. I'm not suggesting that. But certainly, at the beginning it would seem we want to be less prescriptive and the less prescriptive we are, the harder it would be to aggregate. We then kind of dove into what is important in -- in each KPI in general. And we were looking at the KPI that were given to us and saw that they were basically -- what is the key performance indicator and what is the metric. But there was no goal associated with it or no threshold of acceptability. And we thought for post market purposes if the FDA is going to be looking at this key performance indicator over time, it would probably be important for them to understand what is the company's perspective of threshold of acceptability so that FDA can say, 'Oh, that's outside of the threshold of acceptability, let's go figure out why or let's have a conversation with the company.' And also,

what's kind of an acceptable -- or what's a normal error rate, what's a normal standard of deviation again to provide context? We talked about the KPI should be normalized in some way. And if you're a company whose products are not yet in market, you should have like a sense of what your KPI will be, but just because you don't -- you haven't measured your KPI yet shouldn't be a limiting factor of you getting into precert, but you should -- you should be able to just say, 'This is what we expect our KPI will be' and also there should be an understanding that companies should be agile about their KPI and the KPI should be able to evolve over time when they come to market and later. We also acknowledge that the KPI might not be self-evident, which might make it hard to aggravate, which we don't recommend but regardless it might be hard to interpret at all. And so if a KPI is not self-evident, then it should probably be accompanied by a paragraph that describes what this KPI is. And when determining KPI, the company should be thinking about processes that --

within the company that specifically seem to impact risk, things -- and also things like time to response to some hazard that has occurred seems to be particularly important. There was kind of a request of the FDA that the FDA produce some documentation or recommendations or just examples of what KPIs are being used and that those be regularly updated and a note to Linda from FDA, Group 6 run by Adam is the best.

MS. CRUZ: Thank you for the editorial.

MR. BERNSTEIN: So Danny from metaMe Health, Group 1. We were also dealing with mapping and aggregation. And it was a very energetic group with a lot of great information. I think looking at the sample on the sheet, some of the comments were the numbers here are absolute, there's no denominators, there's no total number of users or per incident. And so that was one issue, I think -- there's no context to overall risk profile. I think the concept of a risk profile became something that I think the group appreciated conceptually and thought -- discussed about third

party accessors. KPI should be company specific, weighted, evaluations of KPI's importance, averages towards safety, qualitative, quantitative KPIs. So, you know, some combination that makes sense around the most important aspects of those metrics. KPIs will become a marketing tool. That's actually a bit of a -- that was a positive, but they -- there's a negative coming up in a moment, ensure that KPIs contribute toward quality products. A tiered precert may not be favorable to small companies. Precerts should not be a marketing tool, for instance, bronze, gold, silver. It should be a relationship between the firm and the FDA in terms of your evolution as a company, but not necessarily something that goes on a website to say we are -- we are at this level. The precert in that case may have a reverse effect, if the metrics -- if the metrics are -- you know, can be used to basically -- you know, we can bend metrics, you know, to metrics if we want to. But the idea is to be focused on true intention. The FDA should have a way to confirm

precert companies, public access to compare precert companies. If two companies are in the same space, perhaps on the website, you know, kind of class compare various products and compare those relatively easily. The European CE certification, I think people start talking about that as, you know, they saw similarities to what we're talking about and what's happening there. And we need to understand what precert is going to offer. I think that was -- you know, I think we're learning about that as we go. Safety, cyber security, clinical responsibility are -- are more -- they should be higher weighted when scoring. I think (inaudible) said that. The FDA should provide information to companies of different sizes on how to -- on how to be precert. FDA still should provide a framework across excellent principles. Companies should be able to choose their KPIs. Again, too much information is not -- an example of dashboards is not necessarily a good thing. So, the example dashboard has nine rows, but there -- there should be some level of, kind

of, a higher level view of that. And then perhaps the ability to then drill in to -- to data from the most important KPIs. And then KPI should be limited to the most indicators and a checklist component for precert and I believe for the most part that's it. So, thank you.

MS. CRUZ: Thank you. Okay, we move on to our last grouping, Groups 4 and 9 considering tiers for precert.

MS. O'CONNOR: Hi, I'm Susie O'Connor from Boston Scientific and our groups were talking about tiered certification. So, we spent a little time in our break-out session talking about what is the real outcome of what we're trying to achieve here and that's really providing a valuable product to users or patients at a faster pace, continually learning and delivering better solutions. And so there's this whole concept of how might we do this and we talked a bit about different ways that we might break out those tiers, first being in or out. Is that really going to change things though? Like is that going

to change the way the products are being reviewed and the feedback we got was, well, no, because there's still going to be a level of review, dependent on risk. We also talked about using the bronze, silver, gold method. And we talked about what does that really mean for your software development teams because if there are these tiers, then everyone's always going to want to reach for the -- the gold, right, and in an enterprise organization, is that really opening up the world to those groups? We also talked about if it's a good idea to break them out into like startup, mid-tier, large enterprise, then we talked about is that really also achieving the goal of this group, how can enable these teams to grow successfully if we're giving them different criteria? And I think based on the feedback we got and the way we were discussing about it, it seems like the tiers ought to be broken out by risk or safety with clearly defined acceptance criteria. And those acceptance criteria should be put out in a very open space so that people can

learn from them and implement them easily. And we talked about how do organizations really certify and what does it mean to become certified? Do you become certified as a organization? Well, that's easy for a startup, right? You might have three, 12 people. It might be a bit easier for a middle size group. But then for an enterprise organization how is that possible if you have so many groups and maybe you're acquiring people all the time or acquiring companies, that becomes very difficult. So how do you break it down, we talked about. Is it the division? Is it the business unit and as we were talking about those types of excellence, what does that really mean and it came down to potentially the product of the product team and how do you instill confidence that those teams are doing the right thing and building product in a meaningful way, you know, like, interacting with users. And so again it came down to putting that information in a readily available place so that teams or product groups can learn from there. We also talked a bit about should

track record play a important role in this and is that fair again to start ups? Probably not. But then the hope is that if people become -- or organizations, teams, whatever the end result is, I know it's still in the works, but if you become precertified then you're instilling confidence with the FDA that as you continue to grow your product you have at least at some level been incorporating those key requirements into development from day one, right? Because if we want to enable lower scale products like general health and wellness software solutions, the opportunity to learn and grow is much faster, right. If you're doing post market surveillance, you're getting real time feedback about your features, about the way your users are implementing things. You might want to change and add more -- or add more features in the next three weeks, but how do you do that for class three? Like, it's a bit different and so also understanding that the level of review is also different. It seemed to us that the right way to

do it would be by classification of the device or the software. I think that is primarily it, yeah.

MS. CRUZ: Okay. Thank you very much. And our last group?

UNIDENTIFIED MALE: I'm not sure I can add a whole lot more to the conversation up here. But I'll -- I'll quickly go through what we came up with. Just to remind you our question was -- our problem statement, 'Should precertification be stage or tiered?' Yes.

MS. CRUZ: Succinct. I like that.

UNIDENTIFIED MALE: So just the -- people were talking about easy entry. And I -- I think one of the discussions we talked, which was exactly the same as the other group with our problem statement, was it's about the risk, the depth of the risk. So, we have, for instance, the LMDRF now that has these levels of risk that might be an appropriate thing to look at, how the requirements are different for different organizations. And so I think that, you know, based on those things, we can look at how the safety issues, we have

transparency and, you know, for instance, the -- how are they using open source and platforms and all these other issues that allow for the future liability of the organization, not necessarily financial and those type of things, but how are they playing in to the community? But to make it easy regardless of the organization to enter into the system and we talked about envisioning basically an entry point where you can do a self-assessment based on, first of all, what risk level product are we and then out of that comes the FDA self-assessment where it goes through these elements so that the system itself manage -- helps the organization manage the complexity of the expectations. And I think that would lower the burden on the people coming into the system and dramatically lower the burden on FDA as well. So …

MS. CRUZ: All right. Thank you very much. Let's give our last group a round of applause. There are a lot of open ended questions. I came out of these discussions, but I think in the

interest of time we'll welcome Bakul back to the stage just for a few closing remarks. Thank you everybody.

MR. PATEL: Wow. Who thought this was going to be hard, right? Now, so seriously I hope you guys saw during the entire discussion what we're trying to achieve. And this is exactly why I started this -- you know, this morning as well as yesterday that we need your help. We need to get as close as possible to how you're doing your business so we can recognize that, at the same time give you credit for that. So, going back to that message and that's exactly where we want to be. How do we get there, I think is going to be a journey we continue to sort of have going forward. How do we sort of take this to the next level? So, I walked away with a couple things just to -- and reflection for all the panels' discussion. I think there's a lot of ideas and thoughts. There's a lot of assumptions as well. Some of those assumptions we had not made a choice on. Some of those assumptions we're exactly in line

with what you guys were thinking. So, how do we sort of take this to the level where we need to be. I think there's a lot of potential with this program. How do we sort of take it to the level that is so close to how you operate, deliver and maintain products that can actually give the benefit that we see, these -- we all think we should -- we should be provided? How do you take that? So, it's less about what we see, what FDA wants to see and I've used as -- all along. It's more about how we as a community should be thinking about, you know, evaluating your peers and being very transparent, what we -- what we should share, what we should be clear about and be open with our users at the end of the day and that's really what we're trying to get to. So, we'll get there. I have a high confidence in getting there. We may not get there 100 percent, so this is the whole concept of having a minimum viable product. But we need to get off from where we are to the point that will actually get us to try this out and I intend to do that. We need to

try this out because we can sit here and talk for another five days and we'll have more questions than answers. At this point I think we need to figure out a point of way to get to a place where we can actually iterate and try and figure out. This is exactly why we're going to do that with nine participants. We'll get these ideas. We'll try to figure out what can we try, what can we not try and figure out what's wrong and then we'll come back and try. I encourage all of you guys to sort of don't lose those thinking hats that you got -- put on in the break-out sessions today. Keep thinking about these because this are not some -- this is exactly why it's not something that we could do or any one individual or anyone can do -- any one party can do on their own, right? This is something that we're trying to figure out how to, sort of, get this in the best place. It is different than what we've been doing in the past. I recognize that. I think -- I had a long conversation with somebody and we talked about this. Like, is this something we've done in

the past, (inaudible)? No. We are taking a holistic approach to give -- sort of get to a different place. So help us get there. So that's what I'll say. But I do actually want to applaud all of you who've been here patiently, you know, working with us, trying to -- trying to understand what we're trying to achieve and two, actually trying to help us build. So can we give ourself a round of applause? Thank you very much. And thank you for actually taking two days of your -- of your busy careers and being here, sort of, for this -- for this event. I think this is -- this is the first of many and we may not do entirely like a public meeting soon, but we plan on sort of having open dialogue throughout and we may actually have small webinar sessions. And we were actually -- somebody was actually brainstorming with me saying you should do unconference (sic), give a problem to people to solve and sort of bring it back. So if you have ideas of how to keep this momentum going, I'd be very open to hear that and we're going to -- we are also going to

try to look at other ways to keep this crowdsourcing continuing going forward. So, thank you again and thank you, have a rest -- great rest of the day.

(Whereupon the workshop was concluded.)

CERTIFICATE OF NOTARY PUBLIC

I, Casey Smith, the officer before whom the foregoing proceeding was taken, do hereby certify that the proceedings were recorded by me and thereafter reduced to typewriting under my direction; that said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

Casey Smith

Notary Public in and for the

State of Maryland

CERTIFICATE OF TRANSCRIBER

I, EMMA KADEY, do hereby certify that this transcript was prepared from audio to the best of my ability.

I am neither counsel for, related to, nor employed by any of the parties to this action, nor financially or otherwise interested in the outcome of this action.

February 12, 2018

DATE EMMA KADEY