Digital Health Center of Excellence Listening Session #1
Moderator: Irene Aihie
October 19, 2020
11:00 am ET

Coordinator: Welcome and thank you for standing by. At this time, all participants are in a

listen-only mode until the question-and-answer session of today's conference.

At that time, you may press star 1 on your phone to ask a question. I would

like to inform all parties that today's call is being recorded. If you have

objections you may disconnect at this time. I would like to turn the conference

over to Ms. Irene Aihie. Thank you. You may begin.

Irene Aihie: Thank you. Hello and welcome to today's FDA webinar. I'm Irene Aihie of

CDRH's Office of Communication and Education.

On September 22, 2020, the FDA established the Digital Health Center of

Excellence also known as DHCoE. The DHCoE is a part of the planned

evolution of the Digital Health Program in the Center for Devices and

Radiological Health. It marks the beginning of a comprehensive approach to

digital health technology setting the stage for advancing and realizing the

potential of digital health.

Today Bakul Patel, Director of the Digital Health Center of Excellence in

CDRH will moderate today's listening session for digital device

manufacturers, developers, healthcare providers, researchers and stakeholders

to learn about the Digital Health Center of Excellence. The FDA will discuss the purpose and functions of the DHCoE and will focus on collecting feedback from attendees.

Now I give you Bakul.

Bakul Patel: Thank you, Irene. If you can get to the next slide, and good morning everybody, welcome to the First Listening Session for the Digital Health Center of Excellence.

I'm joined here today by Dr. Jeff Shuren, Director for Center for Devices and Radiological Health, Zach Rothstein, AdvaMed representing MedTech industry, Rene Quashie representing the tech industry, Consumer Technology Association, Megan Coder representing the emerging field of digital therapeutics from the Digital Therapeutic Alliance, Heidi Dohse representing the patient's perspective from Tour de Heart, and Bill Evans representing the Entrepreneur Committee from Rock Health.

We are having this session today as a panel discussion to discuss two main topics on the goals and outcomes of the Center of Excellence and how best we can collaborate.

But before we get further into that conversation and I encourage everybody to have focus on this - on these two topics we're going to talk today and ask questions, provide perspective. This is a listening session. So I'm going to keep my remarks rather short and give you sort of what we have outlined as our goals, our objectives, what we are focusing on and a roadmap of how we're going to continue to build the Center of Excellence that will actually truly empower everybody.

On the next slide, Irene, I want to share sort of the top level goal for the Digital Health Center of Excellence. We truly would like to empower digital health stakeholders to advance healthcare. We believe digital health has the potential to change healthcare to the next era.

On the next slide you'll see how we are envisioning digital health to improve healthcare. Digital health is a convergence of connectivity, data and computing power for healthcare and it's related use is across the life of an individual or a patient is really moving healthcare from the clinic to the patient and trying to understand patient's behavior in its - in the wild. And really a lot of these technologies have been focusing on prevention and earlier and smaller interventions.

This is all happening with the advent of sensors, computing power and connectivity that is connecting everything together and people and patients together with software.

On the next slide, you will see where we are focusing on in terms of FDA's perspective. Health, you know, if you look at a patient's journey or individual's journey from a healthy living to care to management of their care, FDA has an expectation when it's - it is a medical device, when it is used in a medical device, when the technology is used in the medical device, when its technology and advances are used to develop the medical product that's manufacturing. And then the most important thing that we all are sort of very excited about is how technology can be used to study a medical product.

And last but not least is the emerging area where you're seeing lot of companion and adjunct digital health technologies used with medical products that include diagnostic and therapeutics.

On the next slide, you'll see we'll talk about why the Center of Excellence such an important thing for us to start thinking about. This is as Irene said, is part of the planned evolution for Digital Health Program. We want to drive synergy. We want to align strategy and implementation. And most importantly, we want to make sure that FDA and the community is prepared for the digital health future while protecting patients and maintaining our standards, our FDA standards of safety and effectiveness.

On the next slide, we'll talk a little bit more about, so what is the goal? Our goal is to empower stakeholders like I said before. We want to foster responsible and high quality digital health technology innovation. We're going to do that by connecting and building partnerships. We want to share knowledge and the Center of Excellence can help share that knowledge both internally and externally. And we want to sort of innovate in our regulatory approaches to become the regulatory innovation hub for FDA so we can keep up with this emerging field of technology that raises opportunity and issues that we need to get ahead of.

So that sort of drives sort of this whole concept of, if you innovate, connect and share we truly we believe that we'll empower.

Through this discussion we will talk more about this topic, about what the goals and outcomes we want to see. And we'll dive deeper into it.

On the next slide, you will see here are some of the outcomes we are anticipating. We want to advance science and evidence. As most of you already know evidence is an extremely important thing that sort of help us get that trust and confidence in these technologies. We want to also create a place within FDA that we can rely upon and get access to expertise and knowledge

in this space where the expertise is scarce. We want to make sure that we are aligned internationally as well.

And last but not the least we want to be consistent in application of our policy and (our outside) purchases while helping everyone at FDA trying to beat with the same perspective on how technologies should be evaluated, looked at and what evidence we should consider.

On the next slide, we have been operating under the first four boxes here in technology and policy support. My group in Digital Health Division we've been working on strategic partnership initiative such as Pre-certification Program and we have continued to develop policies.

What we are going to do going forward with the Center of Excellence is we're going to take the operations of the Center of Excellence and also house it within the group, hence providing this connecting place for people inside of FDA as well as people from - external to FDA to sort of get to the right people, right experts in the center in CDRH and FDA sooner and quickly.

On the next slide, so although this is a very, very small print on this slide, I just wanted highlight, very, very quickly the Center of Excellence is actually a virtual Center of Excellence, Virtual Center which allows things that are already happening within the Digital Health Group at FDA. But also allows connecting other aspects of digital health work that was going on across CDRH and across other parts of agency and making sure that we are synergized and aligned with the goals of digital health and the way we want to promote digital health to make sure that the issues, science and advancement happens in a very coordinated way.

On the next slide, you will see how we are thinking about moving forward.

We - Irene can you go forward with the next slide, one more? Thank you.

What we want to do is make sure that those dedicated Center of Excellence resources and virtual resources are available to all within CDRH and all within FDA. We are going to set up an - a virtual group that will address and align our activities to the goals of the Center of Excellence. We would have a Steering Committee in the - at CDRH to provide policy, Horizon scanning and regulatory science agenda.

Within FDA we'll continue to sort of work with an Advisory Group across all stakeholders within FDA to start aligning and synergizing in our approaches towards digital health. As you can imagine digital health is being embedded into a lot of other medical products that FDA regulates. It becomes a resource as we move forward for folks within FDA to start thinking and considering and looking at expertise in this area from one stop - one place within FDA which is the Center of Excellence.

On the next slide, these are kind of the services we're trying to offer to folks from various perspectives. Within CDRH you heard a lot about me talking about leading, building and coordinating. And within FDA we'll - we have - we will support, align and promote and amplify work that's already happening in other parts of FDA ultimately to empower and externally. We want to partner, coordinate and then provide a voice to the work that's already happening and be the bidirectional exchange within FDA and others that have been working in this area.

I'll go a little bit deeper into each of these areas in the next couple seconds.

On the next slide, within CDRH we will be leading and setting strategic direction for digital health. We'll be launching strategic initiatives. You already seen some of the regulatory innovation that we are working on and we'll continue to do that. We'll continue to amplify work that's happening and develop and coordinate cost-cutting digital health policies at CDRH.

For the next slide you will see and FDA will continue to support other centers. We'll align and promote and amplify work that's going on. We'll find synergies and look for synergies where regulatory science exists, for example, and research in digital health can benefit all centers. We want to showcase just like we would showcase for CDRH, we want to showcase the work that's happening in other areas, in other areas of FDA that can be highlighted, that with the goal towards empowering digital health stakeholders to take digital health to a safe and effective way.

On the next slide, for external stakeholders we want to continue to provide the clarity on regulation. We want to make sure that we are building strategic partnerships. And we'll talk a little bit more about that collaboration.

And then we want to communicate our FDA list of interest. We want advancements to happen where patients are served, individuals are served and the healthcare is served in the best possible way.

And we want to do all we can within our powers, within our capacity to make sure that this field collectively gets to the next level with everybody leaning forward.

On the next slide, you'll start seeing some of the areas we're going to start to focus on initially.

And some of this you may already recognize, software as a medical device and software in a medical device are sort of something that we've been working on for a long time.

We also see other things such as, you know, virtual reality, digital biomarkers and other AI such as advanced manufacturing and advanced clinical studies. We want to make sure that we are focusing and promoting advanced manufacturing. We are focusing and promoting digital biomarkers that can be used and remove some of the redundancies in the space and make sure that advancements happen in a very coordinated way.

On the next slide, you will see our plan. I mean we put this out on our web site so most of you may have seen it. Today it's a listening session. I won't read the slide but I'll tell you that our goal towards establishing the Center of Excellence and this is the beginning of our conversation. This is the very first listening session. We'll continue to engage with all of you.

And as we move forward we want to communicate, communicate, communicate. We will be entering into coordination's and building partnerships and then becoming that one stop as we talked about.

I think this is the end of my presentation. I'm going to turn the discussion over to the panel next.

But before I get to that, I want to give you a couple reminders. We are eager to hear from everyone today. Understood it's a listening session but we'll focus on two topics. Topic number one is goals and outcomes of the Center of Excellence. And topic number two is collaboration.

We'll talk in detail about this in the next few minutes. But before I get going - get started with that, I also want to remind everybody on the phone call today who are listening into this webinar and listening session to use the chat window to put your comments, feedback into the chat window in case we didn't get to you to the voice.

After the panel discussion we'll open the mic up for people to provide their perspectives and inputs as we move forward. And we'll turn it over to you to provide that feedback.

But before we get - so let's get started. I'm going to ask each panelist. The format for this panel is each panelist will provide a short perspective on the questions. And then we'll open it up for listening sessions from the audience.

So let's start with the first question for the panel. How would focusing those goals that I just shared in my presentation help meet the needs of the digital health stakeholders?

Let me start with everybody to give me a one minute perspective. So I'll just go around the panel for a second. And we'll start with Zach.

Zach Rothstein: Well thanks Bakul and thanks so much for your leadership on all these digital health issues and standing up the Center of Excellence. I know we're very excited as an industry to see, you know, just how much this can bring to everybody's ability to add clarity and other regulatory convergence in the space of digital health.

In terms of the goals that you've outlined for the center, you know, I think what will be really helpful for the regulated industry that is currently under FDA jurisdiction and is developing new and exciting digital health

technologies is the added regulatory clarity around what these products will be subject to at the FDA.

And then also the concept of international harmonization, you know, your leadership on the IMDRF CMB Working Group and ability to incorporate some of that activity into the U.S. FDA's policies have been really helpful for companies that sell on a global level.

And I think as more and more digital health companies sell in more than one country, having that harmonized approach to digital health regulation will really be helpful.

Bakul Patel: Thank you, Zach. Let's go to Rene, Megan and the Heidi and Bill after that.

Rene Quashie: Sure. Thanks Bakul. First, let me start off by saying that the new center really underscores the importance of digital health to CTA and so we commend you and your leadership for that.

In terms of looking and listening to the goals I think here at CTA we believe the center is going to help foster public/private partnerships which we think are incredibly important in some of these complex areas of digital health.

But also just as importantly create needed pathways for better communication between the agency and the wider stakeholder community. I think when you think about regulatory clarity, coordination and alignment we believe those are keys to moving the sector forward as development of digital health tool increases exponentially in the coming years as we all think it's going to.

So the most important thing here is alignment and coordination in terms of FDA's regulatory approach and messaging regarding digital health which I think will then lead to greater clarity for the stakeholder community.

And thank you very much for the invitation to participate.

Bakul Patel: Thank you, Rene. Megan.

Megan Coder: Thank you. I would like to echo I think other's commentaries here. But I think consistency and clarity are the two most important things that we see right now in terms of this particular issue in terms of looking at this from across agency approach, it's really great to see how NICE approached developing even at the more specific review level of the different teams looking at these products.

I think it'll be important for these teams to not only have consistency in how these products are reviewed across different divisions but then also the type of clinical studies and real-world evidence outcomes are expected from digital health technologies.

So as that is developed more broadly I think the industry will benefit from that clarity whether it's healthcare decision makers or clinicians looking for ways to best assess these technologies or again more from the international approach of the harmonized idea of how digital therapeutics and other digital health technologies are really viewed, assessed and then authorized.

Bakul Patel: Thank you, Megan. Heidi and then Bill.

Heidi Dohse: Sure. Thank you, Bakul. From the patient perspective, the work that the Digital Health Center of Excellence is bringing is an engaged patient today

has access to potentially an implanted medical device, the consumer wearables and mobile Apps that are out there and available and then again environmental sensors.

And so patients have been leaning more on self-care and looking for insights that they can lean on to make decisions during their day and to improve their health and wellness, bringing the innovation that tech companies are bringing and aligning that with what the medical device and healthcare industry stakeholders have been doing.

And I think that this Center of Excellence will be a forum to share ideas, collaborate and bring all the stakeholders together for best practices and what other requirements that the patient community is looking for.

So I'm excited to see what's possible and how the center can help make this happen.

Bakul Patel: Thank you, Heidi. Bill, do you want to add.

Bill Evans: Sure. First, thank you again, Bakul for this opportunity to talk to some of these things. You know we think at Rock Health about this in three parts. You know and as an investor in early stage startups, there's a particular viewpoint and I share that just so everyone sort of knows where we're coming from. I think about it in terms of what this does for producers of innovation in this space. These are early stage companies. I think it creates potentially much more predictable and plan performance.

And so for entrepreneurs and investors that means more insight into the capital needs of early innovation. The better insight everyone has, the faster innovation can go and the more efficiently from a capital point of view.

And the secondary is consumers. And I think of consumers really in two groups. Individuals, of course you and me, everyone as an individual who might be out looking for something digital to help us with a problem but also institutions which actually comprise about 80%, 85% of the market for digital health innovation that's delivered by startups.

And our market research has kind of shown that time and again. So I think actually giving institutions insight into when an FDA approval is appropriate and necessary versus not really clarifies the market in an area that is rapidly changing. And that'll help a great deal.

And then the final is just competition. Creating a clear and level playing field will spur competition that aids consumers and allows the best innovation to succeed in a really streamlined way.

Bakul Patel: Thank you, Bill. Let's dive a little bit deeper into that conversation a little bit and maybe I'll ask a pointed question. You know what plays - a - stakeholder needs like looking at it from a different direction are not addressed by this - by the goals that we listed earlier?

Maybe I'll have Bill and Rene to provide a short perspective on that. Bill, do you want to go first?

Bill Evans: Sure. Thanks, Bakul. And I sort of think about this in terms that aren't so much that, you know, there aren't - the needs that aren't being met but needs might be met differentially right now and that the Center of Excellence has an opportunity to level things out a bit.

And of course, you know, the perspective I have is that of big versus small or incumbent versus new entrant to the space.

And so today I think that there's a great deal of advantage to having scale already in place. Having a regulatory apparatus built into your company requires that you're already a pretty big player. Smaller companies have today or at least historically a harder time entering simply because they lack that infrastructure. They have to develop it and they have to do it or may have had to do it in a particular way.

I think with the Digital Health Center of Excellence and work that FDA has done frankly over the last couple of years already we're starting to see the playing field level a bit more.

But I would say that that's a stakeholder need that isn't explicit in the goals. But it's a potential byproduct.

Bakul Patel: Well thank you. How about you Rene?

Rene Quashie: Yes. I'll amplify a little bit of what Bill said. So I think what I'm about to say is generally captured in the materials you presented particularly regarding amplifying FDA's work and awareness. And I think it's somewhat described in other materials that I've seen.

But I would like to specifically include specifically stakeholder education as a need. In particular, I'm talking about FDA stakeholder education organizations who don't usually as a course of business deal with FDA given the products and solutions they develop but who are now dealing with the agency or are about to deal with the FDA as they develop health related solutions.

And so I've heard from many such tech related stakeholders and I believe there is a lot of misunderstanding and misapprehension about FDA rules and processes. And demystifying some of this would be very productive.

You know we don't need to get into implementation specifics. But I think something for example like the new Center of Excellence hosting a call every couple of months with a specific agenda perhaps around certain product categories could be an effective way of reaching and educating the stakeholders I'm talking about while also hearing their issues and concerns.

Bakul Patel: Great. I think that's a great point I think that you both make. I'm going to give just if you guys can take like 15 to 20 seconds to see if you want to add anything to this. I'll go with Zach first and then Megan.

Zach Rothstein: Yes. Thanks Bakul. You know I think for right now it seems that, you know, the issues that the larger regulated industry would have are pretty well defined within the slide deck that you presented.

But I think, you know, as Rene was alluding to, you know, any additional clarity and insights you can provide throughout, you know, the standing up of this center about how it will function and how stakeholders can leverage it will always be helpful.

Bakul Patel: Great. Megan what about you?

Megan Coder: I'll jump in. Yes. I think building on Rene's comments also I really liked his notion there. And I think my addition would be more from that clinician side. I recognize and appreciate that clinicians are part of this discussion.

But we keep getting questions around well what's the difference between clear versus or approved or prescribe versus authorized or 510(k) versus De Novo and forcing discretion versus something different.

So that clarity too is going to be really critical I think for clinicians and those writing guidelines or other decision makers helping them understand oh, this is the corollary to what we're familiar with and this is how we can best engage with this new category of medicine be it any from these digital health technologies.

Bakul Patel: Great. Thank you, Megan. Heidi before we go to you, and I'll pose a slightly separate question and this may be very much a patient focus, right. So what do you see as benefits of these anticipated outcomes that we have listed in my talk for patients and consumers though are not, you know, necessarily labeled as patients? Heidi.

Heidi Dohse: Yes.

Bakul Patel: Do you have a perspective on that?

Heidi Dohse: I do. The benefits that this, you know, new Digital Health Center of Excellence brings to the patient and consumer community is really it's formalizing many of the things that the patients have been doing by themselves. You know, consumer technologies, consumer wearables and mobile Apps have been available. You know, like the last five years there's really been a lot of innovation. In the last two years these products have become, you know, bumped up against the almost medical grade in the data insights that are produced.

But the benefits now with what the FDA is spearheading through the Center of Excellence is to actually formalize what do data insights mean, how can patients use them, what does it mean for compliance safety and effectiveness and to have those standards. Because when we have, you know, have that information that then gives us a path for how that consumer generated or patient generated data and information can be moved into our medical records and our medical healthcare conversations with our physicians.

So I think this is just going to give us that pathway of unifying what's happening in the consumer/patient available world and traditional healthcare.

Bakul Patel: Oh thank you Heidi. Megan, do you want to add to that?

Megan Coder: I think…

Bakul Patel: From a patient's perspective. Yes.

Megan Coder: I think she had it really well said. I think from the patient perspective too, I can't pretend to speak for the number of patients that exist across the spectrum of different diseases and disorders, the technology types.

So even what patients are dealing with on a day-to-day basis is going to be so unique. And how though we can start create some more categorizations and help them understand how my data is being protected, what data am I giving over, how does this translate into these meaningful actions, what is actionable, all of those questions I think will be very helpful for us as an industry alongside the agency and other stakeholders to really start to hash some of those out.

Bakul Patel: Well thanks Megan. We're seeing a lot of good feedback coming in on the Q&A. And we'll touch on those real quick.

So Zach and I know Rene specifically and Bill, as you guys are also seeing sort of patient benefits eventually sort of result from digital health and what perspectives do you have on the outcomes of the Center of Excellence?

Zach Rothstein: This is Zach. And I think, you know, before you used the word upfront about empowering all different stakeholders. And I think in particular the patients here will be the ones that benefit a lot from having their own ability to manage more of their own health and their data through these tools.

And I think that will come from the ability for all different types of manufacturers and software developers to create regulated medical devices in a more efficient and effective manner because of the way that FDA is putting together their policy.

So I think that word empowerment really rings true I think across the spectrum but in particular for patients.

Bakul Patel: Great. Bill, from your perspective.

Bill Evans: Yes. I agree with what's been said. I would add the word transparency. I think that giving everyone in industry as well as consumers transparency into first definitions. What is digital health?

And FDA has been extraordinarily helpful and crystalizing what the subgroups of digital health products might be, what's - increasingly what's regulated and how to the extent the CoE does two things. It first continues

that trajectory of helping industry. All stakeholders categorize clearly what's digital health and how each group gets regulated.

And second, really an understanding of how to pursue in the regulated space approval. And then there's a number of things to answer and address still within that.

But I think that I'm really excited that that transparency is - the CoE is going to really provide that transparency.

Bakul Patel: Okay.

Megan Coder: Can I actually jump in with one more comment on that one? I think…

Bakul Patel: Sure.

Megan Coder: …that comment is really important. And looking at this idea of I think among patients it's fairly common knowledge among patients that not all tablets and pills that come in the same color, like blue, they don't necessarily serve the same purposes. Obviously medications are for a function, purpose and so forth. I think that notion of digital health technologies, yes, it may look like a digital product but what is its functionality, what is its purpose between adherence, fitness, telehealth, remote monitoring and so forth.

So I think all of those are really important just to build upon what was just stated looking at the education is really important for patients to understand what they're using but then also why they're using it too.

Bakul Patel: Yes, perfect. And if nobody had any other on this topic, any additional thoughts, I wanted to see if…

Rene Quashie: Yes.

Bakul Patel: Go ahead.

Rene Quashie: Yes. Bakul real quick, the only thing I would add to everything that's been said that sometimes when you talk about consumers we think about patients but I think it's important to remember the provider community as well because there's a lot of…

Bakul Patel: Yes.

Rene Quashie: …confusion and misunderstanding regarding the efficacy of digital health tools within the provider community.

Bakul Patel: Yes. And that's a great point Rene. I think that's a great add. There are a few questions coming in or actually perspectives coming in. People are like wondering about, you know, reimbursement. I think that's one thing that definitely, you know, FDA does not do that. But I think we can have a good linkage.

                 You know and maybe taking a small step back and Jeff, turning over to you, we heard the panelists sort of give their perspectives. And we've seen some of the feedback that we've been seeing coming in through the chat window.

                 From a public health and FDA perspective, how would these outcomes align with, you know, sort of the goal of advancing and empowering digital health? Can you give us your thought?

Jeff Shuren: Certainly and I've been furiously taking notes so I'm also going to try to synthesize a lot of the things that I heard. And so kind of taking a step back, I think it all comes down to meeting patient and consumer needs, improving their health and their quality of life.

And, you know, patients and consumers should have digital health technologies that meet their needs and that they can rely on.

So to accomplish that, patients, consumers, and providers need an FDA that empowers and educates them, actively listens to, understands and incorporates their voice. And developers need an FDA that understands and advances and moving science and engage with developers and other stakeholders to provide advice proactively, not just feedback and problem solve in real time and offers predictable, transparent, consistent, robust but appropriately tailored regulatory pathways that optimally are globally harmonized.

And that ultimately the Digital Health Center of Excellence can serve as a leader, a facilitator, an educator, an innovator and a catalyst to help accomplish these goals, meet these needs and achieve these outcomes.

And I think the outcomes all align through the taking of a holistic approach to digital health technologies that would allow all of us to turn the total product lifecycle into a virtuous cycle.

Bakul Patel: Thank you. Thank you, Jeff. That's really nicely, like pulled together.

I think we have a few minutes for this particular panel to sort of or this topic to sort of continue the discussion.

But I think Irene and the Operator if you can open for audience to ask - add their perspectives it'll be great on the topic we were just talking about.

Irene Aihie: Sure thing Bakul. (Chelsea), can you open the line for potential questions or perspectives?

Coordinator: Will do. For comments and questions please press star then 1, unmute your phone and record your name clearly when prompted. If you'd like to withdraw your comment or question press star 2; one moment while we wait on our first comment.

Irene Aihie: Bakul, it looks like we have a few comments coming in.

Bakul Patel: Okay great.

Coordinator: The first participant in the queue is (Paige Griddik). Your line is now open.

(Paige Griddik): Ah yes, can you hear me?

Bakul Patel: Yes, we can.

Irene Aihie: Yes, we can hear you.

(Paige Griddik): Excellent. And thank you so much for this presentation. So I also placed this question in the chat. In Europe we have GDPR and in California CCPA.

Is this Digital Health Center of Excellence a place where FDA might discuss with stakeholders their approach to a data protection regulation?

Bakul Patel: Maybe I'll take that first and since it's a question. I think we're building this. And I think FDA has its boundaries I would say. And, you know, we can talk about it from a safety perspective and effectiveness perspective. Of course, data becomes an important aspect in digital health world and digital world.

I think protection of data at the same time, the liquidity of that same data for evidence generation is going to be really important and a balance would need to be struck.

And I would be open to looking at ways to work with stakeholders to find that right balance.

(Paige Griddik):   Thank you so much.

Coordinator: The next participant in the queue is Dr. (Hokayen). Your line is now open.

(Hokayen):   Hello everybody. Thank you so much for this very, very, very interesting first listening session. I'm looking forward for the rest of the sessions as well and for this roadmap that Bakul has delineated for the Center of Excellence, with Digital Health Center of Excellence.

I would say thank you for everybody and thank you to Bakul and his team for making this happen.

I've been personally involved in clinical trials for digital therapeutics and digital diagnostics. I've been involved in digital health for the past four years. I know it's a nascent field and things are not pretty clear about it. Obviously, everyone's trying to apply common sense, right.

But at the end of the day we would need guidance and certain regulations to, you know, to be clearer than they are today, you know, to guide everybody.

And here's based on this perspective, I have a question to Bakul and to the panel as well about any perspective on the role of the CoE and establishing the regulatory roadmap to getting those products like digital therapeutics especially to the market especially regarding clinical trial requirements.

What would we as clinical research organization, I mean how do you envision the clinical research organization would be interacting with your Center of Excellence so that we can basically give the right advice, design the right trials if needed obviously, and understand better the regulatory roadmap for this?

Bakul Patel: Yes. Does anybody on the panel want to take that?

Megan Coder: I'll let you go with that one Bakul first. I'd be interested to hear the regulatory side of the question. But I really admire the question in terms of the digital therapeutic perspective and the types of clinical trials, the type of endpoints, control arms. How do trial designs [for DTx] differ from other types of [designs for] either traditional devices or traditional medications or therapies?

So these are all questions that we in the industry are looking at. But in terms of the FDA's action I wouldn't want to speak on your behalf either.

Bakul Patel: Thank you, Megan. Look, I think we have to be honest. I think that as we see new therapies and digital therapeutics that have been merged and we're seeing use of digital technologies in the clinical trials, we also have a lot of questions.

A lot of - have redundancies that are going on. People validate tools over and over again for their own intended uses.

I think one of the things we would love to sort of see work, the industry and us to be participating in that activity would be is setting standards. I think this is where, you know, folks like Consumer Technology Association and you, Megan, can come in and start thinking about what should that start to shape up.

And I think the regulatory requirements obviously will have to be an input to that discussion. But I think that initial first common sense, you know, this is what the stakeholders need for the trust and assurance is initially get started.

And I think that's going to be, you know, I think about that as a best practice kind of evolution that we need to work towards together.

(Hokayen):   And are you open to - obviously I've paid attention to the emphasis on communication, right, especially in this…

Bakul Patel: Yes.

(Hokayen):   …period right now. Would you be open to talking with several stakeholders in the clinical research organization world so that, you know, we could at least have our voice heard and, you know, our concerns addressed in terms of, you know, the context that I just explained in terms of clinical trial requirements and regulatory roadmap for digital therapeutics and diagnostics?

Bakul Patel: Yes. What I'm taking away from your question is one thing is collaboration. We need to…

(Hokayen):   Absolutely.

Bakul Patel: We need to work towards that mechanism of collaboration. And I think that's the next topic we're going to talk into the next few minutes.

                    But that's exactly the point is what areas we need to collaborate on. I'm hearing research and studying medical products is going to be one of the biggest areas that I'm hearing that's important.

                    And then finding mechanisms to work with within our bounds of what's allowed for FDA to participate in is going to be something that we have to explore.

                    And absolutely, I would want to make sure that we are working to helping or helping our stakeholders, that includes you and include stakeholders who are researching in addition to the providers that we can start building that, you know, infrastructure in place. So absolutely, I would be - or agree with that.

(Hokayen):   Wonderful, wonderful.

Jeff Shuren: And this is Jeff.

(Hokayen):   I can't thank you all enough really.

Jeff Shuren: Oh and I was just going to add.

Bakul Patel: Yes.

Jeff Shuren: You know that role around "clinical trials" things may change over time as we revisit on regulatory paradigms. You know if we move away from the current

sort of stage gate approach and traditional clinical trials and we really build much more of a learning model through the total product lifecycle. And we're going to be thinking about the generation. Really the way I'd focus is generation of clinical evidence a bit different.

Bakul Patel: Yes, great point. Good point there Jeff.

(Hokayen): Absolutely.

Bakul Patel: Irene, I think we're getting up to our time for the next topic. We'll take one last comment or question before we go onto the collaboration topic.

Irene Aihie: Thanks, Bakul.

Coordinator: The next participant in queue is (Jeanine Moore). Your line is now open.

(Jeanine Moore): Thank you. Bakul, Jeff, I really appreciate all the efforts you've been putting into developing a coherent digital health policy.

Coming from a pharma company one of our concerns has been the inconsistency across the centers. And I was curious to know how the Center of Excellence will help better coordinate more harmonized policies given that the Center of Excellence for Digital Health is not reporting up to the commissioner but to you, Jeff.

So what types of strategies are you thinking about so that we are better harmonized across each of the centers?

Jeff Shuren: Yes. That's a great question. And I think, you know, in Bakul's presentation he talked about some mechanisms for having a much more fluid engagement

across the FDA on these issues, one of them being the creation of that sort of Advisory Group within the FDA for the Center of Excellence.

And I think it's through those mechanisms that we as an agency are going to progressively move forward in lock step. Even though we may be dealing with, you know, somewhat different concerns and issues, the opportunity to be far more consistent and harmonized is going to occur as this becomes more of a routine day-to-day activity.

And that's one of the exciting roles that the Center of Excellence is going to play.

(Jeanine Moore): Thank you. And so is there an opportunity for the industry to communicate with that committee or is that through your internal mechanism?

Jeff Shuren: I think that's some…

Bakul Patel: I…

Jeff Shuren: That's, you know, a really great point that I - well I'll let Bakul jump in too. But that is something we should have a discussion around those opportunities to have much more fluid and broader interactions across the FDA.

Bakul Patel: Yes. I was going to just add.

(Jeanine Moore): Yes because…

Bakul Patel: Say exactly that, Jeff. And (Jeanine) I think your point is right. I think in addition to having communications and input and bidirectional channels of information flowing back and forth for the Center of Excellence, I think that's

equally important to think about how that group and/or the Center of Excellence can engage with, you know, folks external to that group.

So to be defined, I think, you know, this is the beginning of the conversation. And we'll continue to sort of explore best ways and mechanisms to set that up. And I think the need is there obviously.

(Jeanine Moore): Yes, right. The need is definitely there because we're having this increasing convergence of digital technology blending with drug development. And you, CDRH has made a very cogent and coherent policy.

But when we interact with the other centers basically it stops with CDRH. Even when we're developing our own medical devices it doesn't seem to apply.

So I think there needs to be some more engagement and discussion to try to understand where our barriers are. So I'm happy to participate in any of those conversation if the opportunity arises.

Bakul Patel: Absolutely. No. Thank you. Thank you, (Jeanine). Why don't we move onto our next topic of discussion which is kind of heading in the conversations around - revolving around collaboration?

And without, you know, getting down into the details of, you know, what it is, and how we exactly do it at this minute, you know, Jeff I'm going to turn to you and just have you share your thoughts. We've been - CDRH has been and FDA in general has been, you know, collaborating with stakeholders all along. I mean FDA I know we have engagement with standards community. We have engagements in the public/private partnership. We also have a program on collaborative communities.

What can we do as an agency and what can we not do as an agency? Can you just set the stage for us so we can have the next segment of our conversation a little bit focus and give people an idea of our limitations and our opportunity?

Jeff Shuren: Well CDRH, I mean we will do what we have the resources to do. But there's always going to be more that can be done. So what we shouldn't do is overextend ourselves, instead be strategic.

One off collaborations can be and they will continue to be important particularly when they involve multiple stakeholders. We tend to get more bang for the buck with public/private partnerships. They can be a force multiplier because they allow a range of stakeholders and depending upon the partnership to share human, financial data, intellectual resources, as well as provide efficiencies for undertaking particular projects and work streams such as through existing contracts.

And we believe the same greater bang for the buck will hold true and hopefully even more so for collaborative communities which is something that's a strategic priority for us that we've been now pushing for the past few years that really is a very different approach on collaboration at least for government where instead of government being command and control and then bringing in partners, instead it's the community that really takes charge in solving shared problems, achieving shared outcomes and government has a seat at the table. We're just a member of the community. And we kind of view it as truly emblematic of what representative government.

And now several have been established and we have signed onto to be participants. And it's my hope we're going to see more of this collaborative community approach merge in the digital health space.

And then I think overall as we take advantage of what you get in the digitized space and that's our opportunity for engagement in a much more fluid real time fashion.

So I think collaboration is going to start to change when we move to these models like collaborative communities.

But I also think the experience and the interactions are going to change too as we take advantage of the very technologies that we're helping to facilitate come to the marketplace.

Bakul Patel: Right. Thank you. Thank you, Jeff. I think that sets the stage nicely.

I'm going to split the next conversation into two parts. The first part is, you know, what are the areas and topics that we should be collaborating on.

And I'm going to turn to Bill, Heidi and Rene. And then, you know, turn the next topic is like okay how can we do this.

So I think (Jeanine) and others who sort of commented earlier started that conversation already.

So, you know, Bill I know you may have to drop off to catch a flight. But, you know, are there topics that you would consider that, you know, that would benefit the advancement of digital health in short-term and/or in the short-term that we should be taking on?

And maybe you can even highlight any long-term ones that you may have. So Bill, can you share your perspective?

Bill Evans: Sure. Yes. So I think that there's so much that's been put in place in the last few or several years ago by Congress that, you know, is in implementation. But so my theme is here there's still more to do in terms of implementing the guidelines that as I understand it were put in place by the Cures Act for example.

And so I think sort of thing of three areas around this, Bakul, you know, a first might be or no particular, you know, the new regulatory framework around AI and ML, and software as a med device. I think is extraordinarily helpful. I think there's more work to be done there. I think that innovators in that space are - have seen a lot of change in a positive direction but still more to be done.

The second would be and again guidance around wellness versus regulated Apps has been really helpful especially in recent months. I think there's still more work to do there as well to help put a clearer line in some cases between what's wellness and not regulated by FDA versus what software fits clearly within FDA guideline - clearance.

And then the third would be more broadly sort of in pre-cert, you know, I think are the companies that we interact with are really intrigued and excited about it. I think one of the things that they want to know most would be what are the sort of quality and operational excellence standards for pre-cert and how can they be sure that they're adhering to those? You know, nuts and bolts type stuff like is ISO-13485 going to get them that gold star or a CE mark that aligns with IMDRF and some other things.

So they're looking for - now they understand what the framework entails, they're looking for some really clear signals about how to proceed.

Bakul Patel: And that's helpful. Heidi from your perspective, what would you say the top
                 things we should do on topic areas for collaboration?

Heidi Dohse: So I think there's two areas that I see that could be beneficial for
                 collaboration. One is looking at how digital health technologies and
                 innovation is going to enable new channels for both healthcare and wellness
                 delivery.

                 And I think we're going to see quite a bit of this in retail delivery of
                 healthcare and wellness. So we're starting to see more retail stores and things
                 like that having like a Minute Clinic or, you know, a place where a person can
                 come in, shop for groceries and go get some, you know, healthcare guidance.

                 So how do - you know, digital health and digital health insights are going to
                 make that possible. How do we bring that into the conversation?

                 And then the other area is looking at other communities that have been
                 leveraging what we're calling digital health but as, you know, in ways that can
                 share best practices.

                 And in this I mean in addition to being a patient, I've been an athlete for many
                 years. And so I look at how I've been using my wearable devices for
                 performance insights and my mobile Apps and how I communicate and work
                 with my coach to reach performance goals. Much of that is very similar to
                 how we as patients want to be able to have insights collected during our day
                 and have specific data points that we can then better communicate with our
                 physicians.

So bringing in some of those lessons learned and how we can, you know, really improve and streamline the patient provider communication leveraging digital health solutions.

Bakul Patel: That's really helpful. Rene, do you want to add anything there?

Rene Quashie: Yes. Yes, real quick. So CTA is ANSI accredited organization meaning we can develop voluntary standards much like other organizations such as UL. So we really believe that the importance of developing industry standards. One of my colleagues always talks about standardization for innovation, meaning that standards actually promote innovation.

So for us at CTA I think there are many issues for potential collaboration particularly on the standard side. But the two that jump immediately to mind are AI/ML, and digital therapeutics for many of the same reasons. First, we're seeing tremendous development in both those areas.

Second, both those areas are showing great promise to positively impact healthcare.

The third, however, both areas also implicate many important regulatory and policy issues.

But the good news is there are many serious existing industry efforts underway to address these issues. So I think it would be relatively easy for the new center to engage with these efforts and provide better opportunity for public and private partnerships and collaborations you discussed, Bakul, but particularly focus on these I would call really truly emerging areas.

Bakul Patel: Yes. That's really important sort of that you pointed out that, you know, where the emerging spaces are actually trying to create new questions. And I think the collaboration makes a lot more sense.

Zach, and from your perspective, and Megan.

Zach Rothstein: Yes. I think Rene did a nice job highlighting two of the major themes that are kind of new to the industry. But I would still add clinical decision support as another item that we can further advance.

And in particular what I envision based on your slides today, Bakul, that the Center of Excellence might be able to assist with is two things. One is in terms of AI, ML and CDS, coordinating more with for example the Center for Drugs. And a lot of those tools are used both they might be regulated as a device but they also might have some drug implications involved with them.

The other part of it is the patients and the caregivers. And having those stakeholders involved in some decision making and policy setting around these types of technologies. I really think, you know, having all of those various stakeholders at the table will make for better policy and add trust and value to the entire ecosystem.

Bakul Patel: Makes sense. Yes. Megan.

Megan Coder: Yes. I think Bakul, all that you and Jeff have done even leading up to the center has been incredible, like you have been so open and welcoming of all these discussions. And for your willingness to learn has been appreciated.

And I think that with the center it could move us now more from this information gathering phase into more of an action oriented approach. So

looking I think at real-world evidence as another example here, digital therapeutics example can generate incredible amounts of data and a large variety.

But what data should be specifically generated for a regulatory purpose versus healthcare payer purpose or an academic purpose. How should available data be translated into real-world evidence that's formally recognizable?

All of these ideas I think will cut across many of your areas of focus that you laid out earlier today and really bring greater clarity.

So I think this is an exciting opportunity where we can go from great discussions and great insights into this action oriented let's move on some of these and then obviously looking at the international perspective. I'll hold off on some more commentary there.

But I think there's a lot that we could do and taking some of the existing frameworks right now for drugs and hardware and identifying how could those be adjusted and modified to really fit the needs and purposes of digital health and therapeutic products.

Bakul Patel: Yes. No. Thank you. Thank you, Megan. Why don't we just, you know let's dive one level deeper and then just talk about, you know, Jeff laid out, you know, best way to collaborate is, you know, in the collaborative community space and in a model. And there are standards activities that we get engaged in.

Are there - what do you guys think about, I'm looking at the panel and saying, you know, for Zach, what other mechanisms that may be existing out there that you think that we could engage in? Of course we can't stretch our focus

in from the Center of Excellence perspective or FDA perspective. So where do we get our best bang for our buck and where do we sort of bring together the right level - right, you know, type of stakeholders together so we can have this robust conversation and solve problems together?

So Zach, do you have ideas and thoughts that you could share?

Zach Rothstein: Yes. Thanks. Thanks Bakul and it's so good to hear that FDA is thinking about this question. You know I think doing these types of stakeholder calls and updates with an interactive Q&A with the - with anybody who wants to participate is a really good process to have that type of collaboration with the various stakeholders.

And I would encourage FDA to periodically host more of these sessions with updates and new learnings that you might have.

Bakul, you and the team that you lead at FDA is very, very active in the community. And we all see you at various industry events. And I would encourage you and your team to continue participating to the extent you're able to and maybe now it's even easier because so much is virtual but to continue to participate in those industry events.

But ultimately, you know, I think FDA is the strongest convener of any of the groups that are on this panel. I mean you have the power and the draw to bring all the various stakeholders under one roof.

And so whether it's more calls like this with open Q&A, whether when eventually we can get back to the great room at FDA's campus and have maybe in-person meetings and breakouts, I think, you know, you have done

          this in the past with other topics around digital health. And I would just
          encourage that you continue to do that with the center.

Bakul Patel: Okay. Well thanks Zach. Megan, do you - what thoughts do you have? I
          know, you know, Digital Therapeutics Alliance is, you know, new and young.
          So how do you think about this?

Megan Coder: Hey. I know. We celebrate our third anniversary in five days. But that said, I
          think one area that I have been intrigued by. And Bakul this comes back to a
          panel that you and I did a while back with NICE from the UK.

          And I love the idea of bringing together groups such as the FDA with other
          international agencies. And I think the IMDRF which I know you, Bakul,
          have been very involved in is a really critical group here.

          And the type of work item that IMDRF had looked at including software as a
          medical device and others now looking at security AI, ML and so forth are
          going to be really critical.

          And given the propensity of digital health products to be used in a cross-
          jurisdictional manner, having these types of frameworks be it building off of
          the MDSAP Program of looking at how pre-cert or how other aspects of these
          different definitions of digital health technologies are coming into play here,
          how those could be incorporated and looked at from a multijurisdictional
          approach.

          Echoing based upon Zach's comments. You have been really at the center of
          lobby discussions. A lot of eyes are on the FDA. So if there's a way that we
          could have a multiagency collaboration which has already been established
          we, as the Digital Therapeutics Alliance, and I'm sure many other agencies,

associations, organizations, would really appreciate ongoing international leadership in this regard.

Bakul Patel: Yes. No. Thanks Megan. I don't know. Bill, if you're still on, do you have anything else to add to it? I know you may have dropped off.

Bill Evans: Still here, still here.

Bakul Patel: Okay.

Bill Evans: And I will add one other thing and it's parallel review. And I'll echo everything the others said, yes to those things. I think parallel review with CMS has the potential to reduce the costs of innovation in a pretty substantial way by virtue of enabling an innovator whether at a large company or certainly at an entrepreneur and a small company to make a single investment or a package of investments in evidence generation that is both clinical in nature for safety and efficacy. But also economic in nature that demonstrates the outcomes that a payer, like CMS, is going to want to see.

That parallel review has of course the potential to get through a CMS reimbursement at the same time as an FDA clearance or approval. But it also will signal. It has this other benefit with a spillover that it signals to the private payer market a willingness to pay that accelerates adoption with consumers when reimbursement through payers is necessary. I think parallel review is the short answer for me.

Bakul Patel: Perfect. Yes. No. Thanks. Thank you. Others, do you want to add a few? I won't call anymore and before we go to an open audience or a question, anything else anybody wants to add?

Heidi Dohse: Sure. This is Heidi. You know prior to my jumping in and focusing full-time on patient advocacy, I come from the tech industry. And I just think that there's such a great opportunity for the Digital Health Center of Excellence to, you know be that forum where you bring tech and healthcare together to really learn the - to kind of work together on the same timelines. And understand each other's business processes, regulation and compliance so we can really bring this innovation more quickly to market with the understanding of, you know, how a tech company will bring something to healthcare and how healthcare can develop requirements in a timeline that can be executed by, you know, the digital health companies.

So I just feel like this is going to be a great opportunity to bring all the stakeholders together, learn the same language and really innovate in a collaborative way.

Bakul Patel: Yes. That makes complete sense. Why don't we - Irene, can we open up the lines for people to provide their comments and perspectives? I think this has been a robust discussion. And I like to hear from the audience as well.

Irene Aihie: Sure thing. (Chelsea), could you please open the line for our participants?

Coordinator: Will do. As a reminder, for comments and questions please press star then 1, unmute your phone and record your name clearly when prompted; one moment while we wait on our next comment or question.

Bakul Patel: Okay. Well while we're waiting for the next commenter to get in the queue, Rene did you have anything to add?

Rene Quashie: No. I echo everything everybody said. I'm wondering whether or not given what Jeff said about the FDA, the new center cannot be everywhere, if there is

any value in the center developing some criteria for how it will become involved in more formal industry efforts. Sort of building a framework around the efforts it is more likely to engage in. That also could be very useful for the center in sort of eliminating other industry efforts that may not be worth its time at the moment. And focus on sort of more mature or ongoing efforts.

Megan Coder: Well even the link established between those.

Bakul Patel: That's a great, great point. Yes.

Megan Coder: Yes. I like that Rene. I think there's value in the divide and conquer but making sure there's harmonization amongst that process is going to…

Rene Quashie: Yes.

Megan Coder: …be really important so we can all know where we need to head but heading there together. Given how aligned we all have been on today's call I really support what you just shared there.

Bakul Patel: Yes. I like the suggestion. Perfect. Do we have anybody on the line?

Coordinator: The first participant in the queue is (Sandy Radusky). Your line is now open.

(Sandy Radusky): Hello everyone. Thank you for the very interesting presentation. I'm a Medical Officer in CBER.

And since we're talking about collaboration will there be any opportunities for reviewers to offer ideas for consideration to be developed for digital health?

There's a lot of times when I'm reviewing files that I, you know, I have ideas that I think would be really helpful to clinical trials. And I just wondered if there was any way to do that.

Bakul Patel: Absolutely. I think the question and (Sandy), thank you for asking that question. Think - I think the panel will be very thrilled to sort of hear that, you know, just like people outside of FDA are interested in collaborating I think people inside of FDA just like the fact that you had raised this question is going to be really important for the Center of Excellence to sort of be that conduit and that enabler to make that conversation happen.

So we'll continue to do that. Yes, there will be a mechanism. And I will actually since you're within FDA and with - and at CBER we would probably work with you all to understand how best to sort of do so and know what ideas you have and communicate that and provide a platform for that so absolutely.

(Sandy Radusky): Thank you.

Coordinator: The next participant in the queue is (Scott Robertson). Your line is now open.

(Scott Robertson): Hello. Yes, and agree, very nice presentation. Thank you for this opportunity.

One thing it was briefly mentioned by one of the panelists, there's sort of a connection point that needs to happen that's not really been discussed a lot because some of these digital therapeutics are going to be things that, you know, the simple things that augment already existing therapeutics that can be done independently. Patients just can download an App or something that then assists in their therapy.

But there's going to be a lot that are going to need to be coordinated through a healthcare provider.

So connecting the provider who knows some degree of that and the patient, I would like to suggest that the pharmacy can play an important role sort of as a coordinator. They don't need to know the details but they can be a conduit both for an extension of the prescription concept, you know, this is the application they need, and the pharmacy can help the patient get it together or connect them with specific resources from the manufacturer.

I will admit that I do this somewhat self-servingly since way back when I was a practicing pharmacist but now I'm much more into standards and technology. But just offering as a point of that last connection point to get from healthcare providers to the patients is a comfortable environment for the patients typically in pharmacies.

Bakul Patel: Absolutely. Thank you so much for that comment. I will definitely keep that in mind as well and that's a great next topic to think about; other comments.

Coordinator: The next participant in the queue is (Val Vanicure). Your line is now open.

(Val Vanicure):   Hello. Hi. As a CEO of a digital therapeutics company I was wondering how the FDA is planning to work with for example CMS around reimbursement codes especially in the field of digital health, digital therapeutic solutions.

Bakul Patel: Yes. I think Bill brought this up, right. Parallel review is one of the programs that we have that focus towards evidence, right. And I think Bill, you may have some thoughts and Jeff, you may have some thoughts on this too if you guys want to just chime in here on reimbursement portions of FDA's role.

Megan Coder: If I may even just jump in, this is Megan. I think one thing with the MCIT bill proposal from CMS, the Medicare Coverage of Innovative Technologies, there is the opportunity for CMS propose that any product with a breakthrough status could receive four years of reimbursement through CMS.

That said from the digital therapeutic side, my understanding is that unless you have a benefit category this is not applicable to you so therefore digital therapeutics may not benefit directly from this.

But I will turn over to Jeff and Bill who may have just been jumping in also.

(Val Vanicure): Thanks.

Jeff Shuren: Now these are great points. And we have - look, we have a great relationship with CMS. We have had active discussions on a variety of areas including around, you know, coding which I think we all know can be, if there isn't timely and appropriate coding tied to appropriate levels of reimbursement, it can be a barrier to innovation.

And the second piece of course is predictability around reimbursement. You know as Bill raised parallel review, certainly one mechanism not just with CMS but we've opened it up for other interested payers including private payers.

And say, of course, if you meet the criteria is terrific because it provides high level of predictability and, you know, love to see continued innovations like that from CMS. You know there's interesting work stream going on in the Medical Device Innovation Consortium, one of the public/private partnerships we're in. That is around a number of issues linked to reimbursement.

And they just brought in very excitingly Jo Carol Hiatt who used to be with Kaiser to help lead that effort. And that is also an opportunity for some alignments between FDA, CMS, developer community and others.

Lastly I'll throw in here is real-world evidence. I think was brought up earlier in its role with payment.

And I think to the extent that there are efforts that sort of facilitate the generation, efficient generation around real-world evidence, it's just not fit for purpose from a regulatory standpoint but it's fit for purpose to then meet coverage, you know, payer needs, to meet those of also informing decisions by patients, consumers, providers, will get us a long way and that's why I'm excited about our engagement in efforts like NEST and related activities.

Bakul Patel: Great.

(Val Vanicure):   Thank you. Thank you so much. It's very helpful. Thank you.

Bakul Patel: Now we'll take the next comment.

Coordinator: The next participant in the queue is (Jeff Tackle). Your line is now open.

(Jeff Tackle):   Hi and good morning. Thanks for putting this session together. I think it's really exciting turning point in the development of digital health and really exciting.

I wanted to kind of follow-up too from Rock Health (unintelligible). So I work in the third venture-backed (unintelligible) years. And I think one of the things that's most - I'm most optimistic about it is that (unintelligible) there,

you know, and maybe through that enabling a bunch of startups to build with greater confidence and to build better fit for purpose.

My question is around (unintelligible) smaller enterprises whether they're startups or small enterprises, and an observation of the Software as a Medical Device Working Group which seem to cater largely to, you know, the Apples and Samsung's and the very large health or IT players. I don't have any great answers because I know there's an efficiency problem of how many different constituencies you can work with. And I don't know if it's venture capital or just strictly small business.

But do you have any thoughts about the smaller enterprises are included in the discussion about innovation and driving digital health and it's not just, you know, sort of the known top 10 or 20 players?

Bakul Patel: And I would say in fact when we were looking to explore the Pre-certification Program and develop that program we are actually looking for the wide spectrum.

And we do have not - I mean the big names obviously are on the top. And people recognize them. But there are some very small players also a part of that process. And we are using that as a representation of what we are looking at for software as a medical device in the Pre-certification Program. I think that's what you're referring to.

(Jeff Tackle): Yes.

Bakul Patel: Yes. I think the answer is in short yes. We want to actually enable very upstream, as much upstream as possible, the right investment, the right mechanism, the right expectation so that when people are creating products

they don't - there's not an element of surprise of what is expected of people to do. I think that's kind of what Bill was sort of alluding to is that transparency and clarity is going to be really helpful for people. And we aim to sort of do that.

And I think we have to do it. And I think I would love for everybody to sort of continue to sort of take the learnings that we are sharing and the clarity we're providing and continue to sort of, you know, spread that. I think that's how we will probably in a place where people are educated, people are clear of the expectations there.

So absolutely, that would be a resounding yes to your question.

(Jeff Tackle):   Awesome. Thank you very much. It's certainly - it's the number one issue having raised money a bunch of times here for startups in the digital health space. It quickly comes down to, you know, how does the FDA feel about this technology, where are they headed?

And what's the likelihood that this will be able to navigate that pathway and so the more clarity you bring to that, you know, there's a lot of people and a lot of technologies around the great ideas that want to channel themselves to these problems so I think that's tremendous and thank you for this forum and the chance to speak. Thank you.

Bakul Patel: Absolutely. And, you know, oh go ahead Jeff, please.

Jeff Shuren: Well I was going to say, you know, that level of clarity, you know, our traditional mechanisms, you know, we put out policies with guidance. We have formal meetings like pre-subs. And, you know, particularly in a space where things, you know, move so quickly is, you know, whether or not we can

ever build-out and have the ability to have models where instead of, you know, you're coming to us, you know, we're there where you're doing your work available to provide that kind of, as I said advice, not just simply, you know, feedback.

And could we do it in a way that's fair because we - you know, across developers and in a way that, you know, we're not involved in the actual product development and served in our - in a role as regulator.

But like I say, more is that advisor early on so people can make the smart decisions regarding technology. But that would be a profoundly different model than what we have today.

(Jeff Tackle):   Yes.

Jeff Shuren: And you're looking at an FDA that really sits and works where you are as opposed to you just simply coming to our offices out in White Oak.

And that's probably a conversation, you know, worth having because that will bring that level of predictability, clarity, engagement, to a whole new level.

(Jeff Tackle):   Yes. Tremendous

Coordinator: The next participant…

Bakul Patel: So.

Coordinator: …in the…

Bakul Patel: Sorry. Go ahead Operator. We'll take the last question.

Coordinator: The next participant in the queue is (Anil Avanti). Your line is now open.

(Anil Avanti):   Hi. Thanks so much and appreciate taking the extra question. So Bakul, Jeff, as a former Fed have been following digital health closely. So I had one comment/question.

It seems like in terms of the sort of biggest bang for buck, collaboration perspective as well as on the sort of regulatory side, when we are developing Apps for healthcare the barriers to use are so low. You know it's sort of like no cost to replicate another instance that the circumscription around the difference between safe health IT and the safe use of health IT is sort of very fluid that it seems like the - not only is the object of attention the actual App or the artifact itself that's doing the reasoning but the context in which it's used and how easily it could be misused is also really important.

And so the implication for collaboration and regulation is that perhaps the platforms through which Apps and digital health products are distributed are just as important in terms of collaboration and regulation and actually just standard development in addition to the products themselves. And that's probably different from the sort of the medical device paradigm.

And then secondly, you know the - being where the product development is actually happening it may be not the best example in the last couple years but if you looked at collaboration with the FAA and how their safety paradigms work in safe - post-marketing, you know, safety as well product development so those are the two questions.

Bakul Patel: Yes. (Anil) I think thank you for that comment. I think you just laid another engagement sort of and collaboration aspect is about, you know, with other

federal agencies and other parties who are increasingly interconnected with the health space, with technology.

And I think you're absolutely right. We are looking at. We're not - we have for example in cybersecurity we are engaged with healthcare sector with large and (unintelligible) sort of work that's been going on.

And I think we continue to do that. I think this is a space where connectivity is truly ubiquitous. And we'll end up learning a lot from other areas that we have not traditionally needed to learn in medical devices and all medical products in general so great, great point.

We are at the top of the - actually at 12:30 so we're at the end of the session here. I just want to take a minute to thank everybody on this call who had provided the great insights and the comments and seeing coming through have been incredibly helpful. And I want to take a minute to thank all the panelists who have been, you know, providing some really great insights and, you know, comments.

Before I close, I just wanted to say that this is again the first listening session. We have another one coming up in November, on November 12 at 1 o'clock. And we'll probably dive deeper into in the next topics. And we'll continue with this collaboration topic. But we'll probably add another one as well.

But I think where we're leading off today is a great starting point for all of us. And what I heard today is clarity, understanding new opportunities, understanding where the intersection happens between different aspects of the patient/providers as well as opportunities for us to start thinking outside of the box to see where we can, you know, learn, and what FDA can learn and move

away from just the info gathering space to actually executing. I think what Megan said makes a lot more sense.

And more to come and I think I'm looking forward to working with all of you to make sure that the Center of Excellence can actually truly serve all our goals, empowerment that we started off with.

With that, Jeff did you have any last thoughts you want to share on this panel today?

Jeff Shuren: Just to add my thank you to everyone and, you know, again this is a continuation of the journey and we will have lots of opportunities to be working together and moving forward and a lot of exciting developments underway. So I appreciate your time and attention.

I'll take a second for a quick plug on the last question for FAA. We're very interested in that model, have been for years. And we're in the early stages to see if we can design something similar for not just the digital health space but I think health technology (at large). If you're interested, check out MDIC's Case for Quality and look under MDIAS, Medical Device Information Analysis System, is one of the early pieces for that.

So again, appreciate everyone's participation today.

Bakul Patel: Thank you Jeff. And thank you Irene for coordinating this session today. And I'll turn it back to you.

Irene Aihie: Thank you Bakul. This is Irene Aihie. And we appreciate your participation and thoughtful questions. Today's presentation and transcript will be made

available on the CDRH Learn web page at www.fda.gov/training/cdrhlearn by Tuesday, October 27.

If you have additional questions about today's presentation, please use the contact information as provided at the end of the slide presentation.

As always we appreciate your feedback. Following the conclusion of today's listening session please complete a short 13 question survey about your FDA, CDRH Listening Session experience. This survey can be found at www.fda.gov/cdrhwebinar immediately following the conclusion of today's webinar.

Again, thank you for participating and this concludes today's session.

END