FDA Digital Health Listening Session #2

Moderator: Irene Aihie
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1:00 pm ET

Coordinator: Welcome, everyone, to today's conference call.

At this time your lines have been placed on listen-only for today's conference until the question-and-answer-portion of our call, at which time you will be prompted to press Star 1 on your touch-tone phone.

Please ensure that your line is unmuted and please record your name when prompted, so that I may introduce you to ask your question.

Our conference is being recorded and if you have any objections, you may disconnect at this time.

I will now turn the conference over to our host Ms. Irene Aihie. Ma'am, you may proceed.

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

I am 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 part of the planned evolution of the Digital Health Program in the Center for Devices and Radiological Health. It marks the beginning of the comprehensive approach to digital health technology, setting the stage for advancing and realizing the potential of digital health.

This is our second listening session.

Today, Bakul Patel, Director of the Digital Health Center of Excellence in CDRH, will moderate today's listening session for digital health device manufacturers, developers, healthcare providers, researchers and other stakeholders to learn about the Digital Health Center of Excellence.

The FDA will discuss the purpose and function of DHCoE and will focus on collecting feedback from attendees.

Now, I give you Bakul.

Bakul Patel: Thank you Irene. And welcome, everybody, to the second listening session on the Digital Health Center of Excellence.

Today, as Irene mentioned, I'm going to share just a very brief background on the center of excellence. And for folks who are tuned in for the first listening session might be a repeat, but might it is worth it for others listen to our goals and objectives and outcomes we are trying to achieve with a center of excellence.

Today, we are going to start with that presentation and then we'll turn into a panel discussion where we'll discuss more about, did we get the right goals?

Do we address some of the needs of the state our stakeholders? And then work towards you know how best to collaborate.

Just to set the stage, we think digital health is a convergence of connectivity data and computing power for healthcare and its related uses across the lifecycle of the life of an individual or a patient. We all know digital health has the potential to move healthcare from our traditional settings to the patient's themselves. We are also on the verge of understanding new patient's behavior and physiology in the wild. And then focusing on the prevention and early and smaller interventions.

We at FDA have been playing a role in the space. But more importantly, I think they're their areas of technology that we think that are important for us to get on the same page are set the right expectations and set the site standards.

The areas that I will focus on today are we are focusing on as FDA is planning to use as a medical product, when it is used in the medical product, when used to develop or manufacturing medical products, or used to study and medical product.

As you all know, the current situation we are in the COVID environment. This clinical studies that are happening for medical products is extremely powerful when they are using digital health technology.

And then the last but not the least is the emerging field of digital therapeutics or they're coming to our life as well as digital diagnostics. As we move towards this space, this became a part of our planned evolution of the digital health program at FDA. Here, we want to drive synergy into all our efforts at FDA.

We also want to align strategy and implementation. And most importantly, prepare the FDA for the digital health future.

We still want to maintain our same standard of safety and effectiveness or efficacy as you may as some of you know. Our goals are really to empower all to advance healthcare in the space. So we want to do that by connecting and building partnerships, sharing knowledge and innovating I know regulatory approaches.

We feel those three pillars will drive the empowerment for all digital health stakeholders to advance healthcare as we think the potential is there.

What we anticipate to sort of achieve is to strategically advanced science and evidence for digital health technologies which will drive towards our goal of making sure we have trust in this technology so we can use them to its fullest potential. They also want to make sure that we are not duplicating efforts that are happening in so many areas. Since technology is touching many different aspects of what we considered healthcare, it is becoming more and more important to get aligned and synergize in our efforts.

We also want to make sure that the regulatory apparatus and the instruments that we have, are in alignment with technology and how technology is being dealt up. We all know it is an important aspect of healthcare. And if you want to make sure that we continue to provide the trust and the confidence that people seek from us, as an regulatory agency.

I want to just give you a really high-level overview on, you know, what we think is to be considered as part of our center of excellence functional areas.

Even though we are thinking about just technology support and policy open within FDA, they also think they're unique opportunities that are emerging, such as medical device cybersecurity, machine learning in medical products and not just medical products, but just in the use and making of medical products. We want to sort of look at, how do we advance secondary science? How do you make sure there's advanced manufacturing that can leverage and be leveraged in digital health technology. And last, but not the least, is what is advanced clinical studies look like?

You can see some examples on the slide, which starts to (insilico) modeling and it talks to the real-world evidence that we have been sort of as a center sort of exploring and as an FDA as an agency of exploring. So keeping those, the entire lifecycle of from the concepts to studying to making to be relying on what other products are being used in the field, is really what we're looking at. And as you can see, this shows health touches all areas.

The next slide is really emblematic of how digital health technology is touching all parts of efforts that FDA is involved in. Those functional areas that I spoke about, talked about earlier, is really needs to be coordinated across the domain, through the center of excellence. And that's the role we are going to play.

Within CDRH, within the Center for Devices where most of the work is happening and most of the impact, most of the work in digital health is impacting the center, we are taking our next step towards how do we coordinate between science, our partnerships and how do we sort of make sure policy agenda is set, right.

They're also looking at doing a similar sort of effort across FDA, where we can truly align into a common interest, into our common scientific

advancement. And looking at how do we empower staff strategically, so that we are making sure that those resources are reliable and knowledgeable as we move forward.

Having said that, the hope and the vision and the goal is to make sure that the Center of Excellence becomes a resource to all, specifically starting with everybody outside of FDA, where we want to partner, we want to coordinate.

You want to provide that voice, you know, make sure the science and the requirements and the needs are sort of addressed.

We want to make sure that the FDA wide, there is coordination, we want to support alignment and amplify the work that's happening in other parts of the agency.

And the CDRH, where most of the regulatory impacts are happening with this technology, we want to make sure that we are strategically sort of advancing. We are leading in building and collaborating with other parts of the work that's going on the digital health space.

Now, of course, this is going to be limited to our resources. And of course, it's going to be limited to what we can do. And I'm going to - the Center of Excellence is not going to solve everything, cannot be the center of hub for entire universe, but I think we are this is our first step towards meaning forward creating an environment and creating a platform that we can help all stakeholders sort of advance in this in this space.

And that's sort of the vision.

I won't read through all the slides, but I'll just highlight a few things. Within CDRH, we want to set and lead strategic direct direction. We want to continue to build more capacity and coordinate development across cross cutting digital health policies, leaving sort of the decision on regulatory decision-making towards the review officers who are actually reviewing. And then applies, again, for other centers at FDA as well.

We want to be that resource for those other centers and other review sort of offices that we can provide that technical and scientific expertise. They can provide training and so can grow the workforce. They want to share the resources. When I say resources is not just about people, but also knowledge that we can sort of cut across other parts of agency.

And externally, we want to leverage and stand upon the shoulders of the giants who have been working in this space for so long. And amplify that work. We want to advance international harmonization so that as there's no boundaries known to the space of digital health, you want to make sure they're aligned.

They also want to make sure that, you know, not just the regulatory standards that are accepted, but also International, industry driven, Clinical Standards are also set. And that's what we want to sort of get towards.

With that, I'm going to just give you a view into sort of how we are thinking about moving forward. And you saw this listening sessions that we're holding are actually part of this planned effort towards understanding the needs. And we are going into discussion next in the panel discussion to talk about what does that look like and how do we sort of go forward. And then we continue to build partnerships and sustaining growth.

Again, like Irene said, it's the starting point.

I'm going to turn the discussion over to other panelists. But before I go there, I would have each one of our panelists say a couple words about themselves and their organization.

We'll start with Amy.

Amy Abernethy: Hi, this is Amy Abernethy. I am Principal Deputy Commissioner and Acting Chief Information Officer here at the US FDA.

Bakul Patel: Ray.

Ray Dorsey: Bakul, congratulations on the position.

My name is Ray Dorsey. I am Neurologist at the University of Rochester where I am Director of the Center for Health and Technology.

Bakul Patel: Jesse.

Jesse Ehrenfeld: Thanks so much Bakul. Delighted to be here today.

Jesse Ehrenfeld. I am a member of the Board of Trustees of the American Medical Association. I'm a physician at the Medical College of Wisconsin where I practice anesthesiology and I'm a clinical info management.

Bakul Patel: Rob.

Rob Kowalski: Hey, everyone, good afternoon.

My name is Rob Kowalski. I'm the head of Regulatory Affairs and the US Head of Development at Novartis. And I'm on the panel today representing pharma - the Pharmaceutical Research and Manufacturers Association.

I'm the Executive lead for our Digital Health Working Group at pharma.

Bakul Patel: Thank you Rob.

Leslie?

Leslie Saxon: Hi Bakul. Good morning from California.

Leslie Saxon, Executive Director of the University of Southern California Center for Body Computing Cardiac electrophysiologist.

Bakul Patel: Nilay.

Nilay Shah: Hi, I'm Nilay Shah. I lead our Division of Healthcare Policy and Research at Mayo Clinic. And I also co-lead a joint Yale University and Mayo Clinic Center for Excellence and Regulatory Science and Innovation.

Bakul Patel: Great, thank you, everybody.

And so before we dive into the panel discussion itself, I wanted to sort of provide sort of how the panel discussion is going to go about. So we are going to have two topics in our discussion today.

One discussion on did we get the right goal? Are we focusing on the right outcomes? Anything else we should consider?

And a topic number two is collaboration. How do you work together? How do you guys see us working together internally better? How do you work with all other stakeholders?

So with those two topics - in each of these topics, I will ask an opening question to the panelists. And we'll go with that.

And then after the panelists have the discussion, we'll open it up for public listening session, which means that you can, you'll be provided instructions by the operator to open up your line and you can speak to it. We will do that for about 10 to 15 minutes given the time.

What our request everybody to do on the call today is use the chat window to put in your comments and perspectives, so in case we don't get to your perspective, we at least have them collected. So in that way, we will be able to take that input as we're sort of working towards the next steps of the Center of Excellence.

With that, let me just open up the first opening question on the goals and outcomes. And this question is directed towards Leslie, Nilay, Jesse and Rob and if you can give me a one-minute piece perspective, "How would you see fulfilling the goals help meet the needs of digital health stakeholders as we are designing to do?"

Leslie.

Leslie Saxon: Yes, so I think as you drive a new regulatory paradigm that's needed really for digital health to develop to encourage and incentivize Patient Centered Health or Disease Management Solutions, one of the challenges is going to be incentivizing the promoting this development.

That's really going to be bringing hardware and software together. You'll have approved regulated devices, bringing information to patients, maybe within an app that also brings in diet information or other less-regulated things. You'll be defining new digital biomarkers and therapeutics.

So that the question is that it’s really hard to incentivize this. And I think the needs are going to be clarity into how this is all going to work.

I also think because it's a new area, having the payers alongside at the beginning is critical , because at the end of the day, we're not going to rely on PMA or 510k and all the advocacy data for managing heart failure, managing your performance, obesity, etc is going to be in a post market efficacy data, if you will, the evidence will come later. The naturalistic practice world or in the wild, as you call it.

Someone's going to have to package that up, show an outcome measure, reduce hospitalization, improved health outcomes and then there's going to have to be a payment attached to it.

It's going to be different than FDA approval, CMS, et cetera.

So, it's very complicated question, but I think a really important goal, from the beginning is going to be trying to understand that piece of it. How do you present the efficacy data? How do you get drive approval that will that drive a payment, particularly when there is a - there are a number of different companies or stakeholders that are participating in that outcome, if you will.

So it could be the implantable sensor, it could be the diet app, or drug adherence, all in one solution.

So those are the things I'm thinking about for you know, really clear goals and targets that will incentivize people to come up with these solutions.

Bakul Patel: Great. Thank you Leslie.

Nilay.

Nilay Shah: And think, you know, I think most of us know the digital health world is moving very rapidly.

And especially in the last three to four years, there's a lot of new technology, a lot of new approaches to digital health that are becoming much more than norm.

In addition, I think in your presentation, we sort of showed all the diversity of what digital health means.

And one of the key challenges is depending on the stakeholder, if you're a patient or clinician developer, it's really unclear what the different pieces are. What is regulated, what is not, in what context.

And while there's a number of guidance's that have come out some back in the last two years, it resides in different parts of agencies sometimes.

So having the coordinated center, I think, will be a really great resource to bring a lot of the efforts, both internally within the FDA together, as well as externally to the FDA.

I think this will allow broadly much more rapid development of products, hopefully, and ability for patients to benefit from the development of those products.

Bakul Patel: Great, thank you, Nilay.

Ray?

Ray Dorsey: I think COVID has done many things. One thing it's done a lot is this facilitate accelerate the adoption of digital health.

So, for example, in three weeks the number of Medicare beneficiaries who you benefited from telemedicine increased 100-fold. A hundred-fold increase in adoption pharma medicine in three to four weeks -- an unprecedented change in healthcare delivery on a short period of time.

I think the digital health centers are excellent that FDA - the FDA to take a leadership role as opposed to a reactive role to digital health challenges that are emerging and opportunities that are emerging.

I would highlight three big ones. One is around decentralized trials, just like telemedicine brings clinical care to patients, decentralized trials doing clinical research opportunities directly to patients, I think FDA has a huge role to play to facilitate that transition to a more participant centered model of research that quite, frankly, would be likely lower cost and faster.

The second is around digital biomarkers or Digital Measures. The digital biomarkers didn't measure can give you objective real-world sensitive assessment on the accuracy of a new drug device or other intervention.

And you know, neurologists you know, five and a half million Americans have Alzheimer's disease. And we have you know, highly effective treatments for Alzheimer's disease. 1.1 million Americans have Parkinson's disease most effective treatment is over 50 years old, and neurological disorders, the remaining sorts of disability in the world and yet terrible ways of measuring the disease that are cheaply derived from outcome measures that were developed in the 20th century.

We had tools and technologies in the 21st century that can accelerate the evaluation and development of new therapies for lots of disorders (unintelligible) affect all of us directly or indirectly.

And the last one is around digital therapeutics. (Unintelligible) COVID has really highlighted their potential physical therapy as beneficial as the individual is still very nascent field. And it's great to see the FDA taking a leadership role on that topic, as well as many others.

Bakul Patel: Thanks Ray.

Jesse?

Jesse Ehrenfeld: Thanks so much for having me here to represent the AMA and sort of the physician perspective.

I tell you, when we ask physicians across the country, what's important to them in the use of the kinds of tools that the center of excellence is going to help bring forward into the marketplace.

They wonder that the tools work, they wonder how they're going to get paid for them. And they want to know if they're going to get sued or be held liable?

How do you answer those questions? You answer those questions through regulatory certainty and making sure that there's certainty both on the physician and user side, as well as on the payer side. And I think that was addressed by one of the previous speakers.

So things are all really linked together. And so the degree that the center is going to be able to engender trust, to allow stakeholders to buy into the product development cycle and then ultimately, using the marketplace, I think this is going to be really, really helpful.

It's really important for me, to think that, you know, the way that these changes were using this product has changed markedly. You know, products change over time, we're not used to that as a physician, right.

When I have a tool in the operating room that I'm using, you know, either I learned about it in training, or it's a new device and I get in-service on it. But we're talking about tools that can change over time. And so I think it's going to be really important that the FDA helps the clinician community and the folks bringing these things to the marketplace. Understand how do we differentiate products that change over time, those that don't? What's been reviewed by the FDA, what has not, and make sure that we have pathways to communicate experience with products over time.

You know what, when I was early in my career in training, a lot of talk about, you know, adverse events, how they get flagged, what do we know about, you know, experience with a product.

Now, I think there's an opportunity to experience changes and how we communicate use of products over time, so that there are opportunities to communicate when new populations could find benefit from a tool, or there's a new use for a tool or maybe something doesn't apply. And I think the approach that the center is taking will really open up a lot of opportunities for those things to be more effectively communicated across the ecosystem.

Bakul Patel: Great.

Rob, you bring a different perspective to this. Can you share your thoughts?

Rob Kowalski: Yes, sure. But it actually really capitalizes on, I think, what everyone else has said, which is that first of all, and as you appropriately said, because this is a really broad topic. And I think what the DHCS is trying to tackle is huge. You have everything as, as Ray said, from, you know, decentralized clinical trials to new regulated endpoints.

The tools that we use to new devices to digital therapeutics, that topic is, is massive. But what I think is really timely and I think setting up DHCoE is going to be really critical to make sure that we move in this really, really fast-moving space, in a bit of a judicious and consistent way. Because while it feels we're at the beginning of this journey of regulatory science and new digital tools, I think we're at the bounce point of a pretty big inflection point. And it's going to move really fast.

And I think, as some of the others on the panel have said, this is an area where we can put together a construct or a rubric today, but in two years, it's going to be outdated. And so the frameworks that we have to set up in the beginning are going to have to stand the test of time to some extent.

And so the ability of the DHCoE to put some glue around that consistency across the agency, consistency across different digital paradigm, I think will be really critical for us to move forward. Because if you hadn't put on your seatbelt yet, I'd put it on now because this is going to move really fast. And we're going to have to be agile, if you really want to take advantage of everything that that DHT in this space really has to offer.

From an industry perspective, really excited just to be DHCoE.

Bakul Patel: Great, very well said that, Rob, I think you've kind of nailed it and it kind of trickled back to everything what people are saying I think you've talked about learning regulatory system and an ongoing clarity. That's absolutely a must while making sure the expertise also is there at the center at the agency that can help products get out to the market faster and better.

Let me flip it around a little bit and then ask the question about, you know, what stakeholder needs that we are not addressing by the DHCoE goals that I just shared earlier.

Maybe we'll start with Jesse first.

Jesse Ehrenfeld: Sure, thanks, Bakul.

So, you know, one thing that's really important that we think a lot about is how the physician perspective and the patient perspective, are going to come into the development and regulatory paradigms with these new products. And, you know, education for physicians is going to be really, really important as a new approaches taken.

And so that's one place where I think having some clarity would be really valuable, as you think about the development of the center, how all these things come together.

The other piece that is top of mind for me is understanding what patients want to expect in need. And I hear all the time, increasingly, as we hear about data and privacy and how data is used for my patients that they want to know where their data is going, how it's being used to develop algorithms. And then a physician often find themselves as an intermediary between the device and the patient in the data.

So physicians really kind of get stuck in the middle sometimes, needing to be able to understand how to describe that.

You know, also when it comes to AI and some of the really exciting technologies that are starting to come into the marketplace.

I think, you know, if you have a situation where an algorithm is evolving, or new data is available, and a recommendation might be different a month later than it was today, that figuring out how we communicate that change or not, the patient is going to be really, really important. Because if the answer does change, patients are going to want to know about it.

And that's a shared need. That's going to happen across both patients and physicians, as we think about the, you know, physicians needs in a new regulatory paradigm.

You know, I imagine that standards are going to be really foundational, as you think about, you know, what does the pathway look like for products in the AI machine learning space. And it's going to be really, really critical to make

sure that we meet the needs of giving physicians enough trust in these products. And, you know, people just won't clinically integrate new tools, if we don't have that trust into figuring out that clinical validation piece is going to be an essential component of all of this.

Bakul Patel: Great, thanks, Jesse.

Rob, do you want to add to that?

Rob Kowalski: Yes, I do. Because I think what, what the DHCoE probably came to do is all the work. And actually the details of bringing a new digital health endpoint, for example, to the marketplace.

So you know, if our goal in the end is to bring better endpoints that are more meaningful to patients, whether it's in heart failure, or COPD, or, you know, pick a disease state, better endpoints, and we use today in our clinical trial, so who cares how far someone can walk in six minutes. That's not as relevant as maybe a digital endpoint can actually talk about form and function and a patient's ability to do their daily activities, for example.

But to move the regulatory paradigm from here to here, is going to take a lot of collaboration partnerships across many, many different domains from not just the industry and the FDA, but patients perspectives, academic perspectives and what are these new paradigms. And there's a whole bunch of them that are ready probably are ripe for the picking to actually move to something that perhaps is more relevant.

You know, we've used the crude tools, because that's all we had. But the window that technology opens is I think, really interesting and intriguing. And so I think we're going to see even more and more partnerships formed

and consortia formed to try to solve this, but I want to solve it 10 times for the same disease state, we want to solve it once. That tries to meet the needs of the stakeholders and be responsive to what patients are looking for.

So I think there's a whole another part of this discussion that we'll be defining together for many years to come.

Bakul Patel: Great. Thanks Rob.

Ray, Leslie, Nilay, you want to give a quick snapshot before we move on to the next question?

Ray Dorsey: Sure. So I'll build off of Rob's comments, I think there's two concrete.

The first are case examples of case study. I think that the fact that FDA has approved the digital therapeutic makes it a lot clearer to other people in developing digital therapeutics, what the regulatory bar is. I think one you need good examples and case studies.

The second is I think you need more affirmative guidances. So rather than having the need for better endpoints that digital measures could in many ways be much more valuable than our current measures. But I think we need more guidances and more examples.

I know the FDA, for example, indicated that moderate to vigorous physical activity could be an endpoint for COPD. I think the FDA articulated more of those and actually approved drugs or devices or other therapies based on the endpoint that will be extremely valuable to the field.

Bakul Patel: Leslie.

Leslie Saxon: Hi it's Leslie. I think that within the FDA, it's going to be critical to define the role of the Center of Excellence, review, whatever that ends up looking like, is it an advisory function compared to the core device or drug review group, this is the clarity that people are looking for.

So if you have your device or drug approved within a separate group, outside of the COE, how does, what is the exact process for a review that is an adjunctive app? What if there is an approved device that brings data out of the device for a different indication, for example a human performance indication for a continuous glucose sensor versus a diabetes indication? How does that exactly work and clarity around that is going to be critical to getting these products out and learning from them and learning their value for the patient for diverse outcomes outside of the labeled indication.

So more definition and use cases are great, but literally, who do I call, I have a core device review group, how do I get this done? and evaluated, you know, seamlessly or, , is there going to be a pre cert kind of program like there has been through the COE? You know, what literally, what's the number I call? How does this how does this work?

Bakul Patel: Yes, it makes complete sense.

Nilay.

Nilay Shah: And lastly, (unintelligible) also said, you know, one area that hasn't been brought up as much, and to what extent it fits under the theory would be a question is, for example, there's increasing interest in healthcare organizations and academia and developing a lot of AI ml based algorithms to predict a variety of either diagnostic strategies or treatment strategy.

And so the question is, as these things get embedded in electronic health records, one from building those algorithms in a pure nice data set to what does it look like a live environment? And what impact does that have on patients and how clinicians deliver care?

And to better understand what is - what's the process to sort of manage that and making sure that that's safe and effective, I think will be important, because there's increasing interest, I think, across the country in trying to develop algorithms and put them into my electronic health records.

I think that's one area and then the other just related area. And that is to think about what does the transportability of those algorithms look like, right. If there oftentimes developed based on single helps with some data or single population data. Can you transport those algorithms across, you know, any other population or any other health system and with that the related area is also the issue of algorithmic bias, right via quarter sensors, but algorithms are used or in the context of clinical care.

So I think there's a lot of opportunity there potentially, for digital health COE to sort of, you know, design a pathway for how to move forward in those areas.

Bakul Patel: Great.

I'm going to skip the next question that I was planning on asking about outcomes.

But maybe I can go to Amy now and just ask that group. Amy, you've heard the panelists speak about and give their perspectives. And, you know, I asked this question to Jeff in the last time.

So I'm going to ask the same question to you, from the perch you're sitting in and what you're seeing across the agency, you know, from a public health, FDA perspective, how would you see these outcomes align and from what's your take on these?

Amy Abernethy: Thanks Bakul.

So first, let me kind of hit on what I've heard and how it resonated. And I think that that will also point them to this question around FDA, and public health outcomes. You know, as Rob mentioned, really, this digital health space is incredibly broad. And it's broad, and it's coming at all of us quickly, in a really good way. And COVID has accelerated that.

And importantly, what you're also seeing here is there's many different lenses and other different lenses just on this panel, let alone this the importance of a wider variety of lenses. Even as we start to think about the physician voice, the patient's voice as Jesse brought up. And one of the things I think about inside the FDA is when I think about digital health right now, it largely lives in a series of distinct islands.

So there is the regulatory activity as it relates to medical devices. There are some of our regulatory science activities focused on artificial intelligence. There is their activities in Cedar as it relates to not only questions around, for example, decentralized clinical trials, but also around the role of digital health solutions in marketing. And these are all acting as distinct areas across the agency, that touch on digital health solutions.

But really what they are, sort of if you pull out to 100,000 feet, their signals of how digital health is touching all across the medical products the FDA has responsibility for regulating.

And also importantly, these individual islands are slowly becoming an archipelago. And we also need a coordination, a coordinated voice for how we deal with that archipelago. And I see the digital health center for excellence really focusing and functioning as that coordinated voice.

It's kind of like a federation and sort of organizing the federation thinking. And then, you know, I got to some of the additional comments here were regulatory certainty, which is one of the critical issues that was brought up, the consistent understanding of what it is and definitionally understanding what it is, but also the features, such as what's the features of the data sets, that then are used to build artificial intelligence algorithms and understanding that.

And then also our evolving understanding of the many applications. Importantly, as FDA, we regulate products in the context of their use. The same sensor may be regulated for bias in the device context, but also used in the clinical trials context and have sort of different realities in those contexts. But we actually still have to have a similar understanding of what it is how we think about algorithms and defining what good looks like. And I see the Center for Excellence really playing a critical role and moving that forward.

Also, in line with what I've heard from the panelists, the Center for Excellence has an important internal role of cross pollination and building coordinated familiarity.

Again, it goes along with that definition of what is it and understanding of utility and what good looks like but being able to build that together. And I sort of see that's where this is going.

The last thing I'd say internally at FDA, is that it is a hard job, Bakul, that you have of building all of those bridges. And so it's important that we listen to each other inside the agency, we also listen to our main stockholders outside the agency of what is it looks like to build those bridges. And how can we do that well.

I note that the Center for Excellence also is being built in line with our technology modernization, action plan, and data modernization action plan. And these are all coordinated activities that are being built together to inform each other. And we need to make sure that FDA is technology ready for the plans coming at us.

And then align with what Ray noted that we're all exploring the different case studies or use cases that are possible. And we're also in line with what I've heard many different ways here, the building of the external bridges.

So finally, that kind of takes me back to how do I see this in line with FDA opportunities and outcomes, public health opportunities and outcomes. I think, really, we all want to leverage digital health as a critical path towards innovation and better outcomes.

And from the FDA side, the digital health center for excellence helps to ensure that we can chart that course efficiently. And in a more coordinated fashion, we can be learning from each other inside of the agency in a thoughtful way, which I think is good for everybody.

I think the other thing is, is from an FDA perspective, help to make sure that we are able to not only be efficient, but not be a roadblock. In other words, coming up with the creative strategies that are going to need be needed, so that we can move digital health forward.

From a public health perspective, we actually have to be thoughtful in both directions. Not everything is going to be helpful. Some elements in the digital health space may do harm. And our responsibility as the agency is to make sure that we promote and protect public health, we ensure safety and we ensure that effective products are getting to the patients who need them and that innovation is happening.

And so importantly, with all of our responsibilities on the regulatory side, I see the digital health center for excellent, making sure we've got that know how to do that work of protecting and promoting public health.

Bakul Patel: Great, thank you very much, Amy. I think that's a very well rounded out in terms of how, how we look at it things and I think there's different perspectives for you know, how we move forward. I think as we were building it makes a lot more sense.

I'm going to open it, open it up for the audience to provide their perspective as well. So Irene and operator can you just open up your lines?

Coordinator: If you would like to ask a question on the phone, please press Star 1. And please record your name when prompted to be introduced. Once again, please press Star 1. And please record your name to be introduced if you'd like to have a question or comment.

Bakul Patel: Great. And while we're waiting, I'll just remind people that we won't be able to get to everybody on the call. So please put your comments in the chat window so we can at least have them.

Great. Operator, do we have anybody lined up?

Coordinator: We have a question from (Caitlin O'Connor). Your line is open.

(Caitlin O'Connor): Hi, there. Thank you so much.

My name is (Caitlin O'Connor). I'm an attorney with Nixon Grout Law. I first of all, just want to thank you guys for having this panel today. I think that everything that I've been hearing is really exciting.

My main question for you all is whether or not you have thought about or plan to collaborate with CMS at all, in addition to the efforts that have already been established, as far as making sure that reimbursement is very available to health care providers and coverages available to patients to make sure that even when the FDA put these new devices and everything through its process that patients and providers also have access to the technology as quickly as possible.

Bakul Patel: Yes, I don't know if anybody on the panel wants to take it. But Amy, do you want to start with that?

Amy Abernethy: Sure. Thank you.

So one of the things of great interest to us at FDA is to continue towards working on CMS and FDA alignment, we actually are exploring how we can

use the same real-world data sets in service of the tasks in the post marketing space.

In particular, the FDA has identified a need for as well as evidence development tasks that CMS has identified similar check coverage with evidence developers development schema. And we see devices, especially the big breakthrough devices, including the spaces involving digital health, as really an important place to explore and potentially take that forward.

And I would say that this is still in its infancy and in development. But we see it is really important, especially as not only are there going to be more and more innovative technologies coming through, but also many of these technologies naturally generate data that can help with their evaluation. Or we can be thoughtful in the development of the corollary data collection activities to be able to align and have dual purpose data for both CMS and FDA.

Bakul, back to you.

Bakul Patel: Thanks, Amy.

Anybody else on the panel want to comment on that?

Leslie Saxon: Bakul, it's Leslie.

I think COVID-19 has been an interesting test case. Will payers continue to now they're operating under waivers, pay for telehealth experiences as they have been necessitated by COVID-19?

Things like extending acute care models into the home, that extend existing hospital licenses, and pay for home acute care due to strained hospital resources, will those types of flexibilities extend beyond the pandemic or -is everyone just waiting for it to go back to the old business models as usual?

Hospitals make money on acute hospitalizations and surgeries. And ambulatory telehealth is not a priority because that's not a profit center.

As I think of the massive transition that will have to occur for much of healthcare delivery to be free of bricks and mortar for many different types of acuity, digital health solution models of care will be critical here.

And I don't think we know but legislative activism is needed here in order to make sure that payment for these types of remote care solutions happens.

Bakul Patel: Yes and before we get another caller on the line, I would say thank you for that comment Leslie and Amy.

I think I was adding I think - just like we were talking, I mean, last time we talked to the industry, the investors, this time you're talking to providers and researchers and perspectives from other perspectives.

We do feel - there's another group of stakeholders that we feel will touch the center of excellence with touch is other government agencies. And beyond just CMS, we heard it very loud and clear last time about, you know, reimbursement becoming sort of one of the biggest next step to sort of solve in the space of digital health.

I think that's largely more good than bad, right?

I think you'd think about research that's funded by the purchase of HHS. And you know, there's work that's being done in other parts of federal space.

I think we do need to sort of make sure that the equal amount of touchpoints that is going on - of course and Rob, I would completely echo what you're saying, you know, we will not be doing all the work.

In fact, we will not be doing the review. But I think Leslie's point about making sure when there is a review of a product happening, when those when we can provide the support and advice and help to those review offices is going to be critical. And that's where we're trying to set up.

Can any other call on - any other caller who wants to give their perspective?

Coordinator: We have one from (Sierra Saltin). Your line is open.

(Sierra Saltin): Hi, thank you. Bakul and Amy, thank you so much for holding these sessions are really very helpful. And I look forward to more of them in the future.

My comment would be that one of the things we think the center of excellence can do is really help Congress understand more about digital therapeutic. Leslie actually just made the point, you know, the need for legislative activism. And just earlier caller talked about reimbursement.

There is already as Bakul, you and I have spoken a little bit about, legislative effort underway now on digital therapeutics being reimbursed.

And I find that all the offices I'm meeting with up on the hill have very little understanding and they're trying to differentiate the world between so called good actors and bad in the digital therapeutics area and are using made up

terms to refer to these therapeutics instead of using FDA terms and trying to understand, trying to create definitions when they aren't needed or thinking that the best answer is they have to be prescribed by a physician to be a good actor, if you will, rather than you know, prescribed or dispensed, drawn to the direction of or recommended.

Or they think that only clear devices, but not those subject to the April 14 guidance are good actors.

So I think this is anything you all can be doing to help spread some of your expertise as they are legislating would be really helpful.

Bakul Patel: Thank you for the comment. We'll take another comment before we move on to the next panel discussion.

Coordinator: It's from (Sanjay Sarma). Your line is open.

(Sanjay Sarma): Hello, thank you. This is (Sanjay Sarma) with Ryangold. First of all, thanks for holding these sessions very informative, and looking forward to continuing to engage with you all.

My question is just a really simple question around how the COE he plans to engage with the patient and provider community at large? And specifically, what influence will that engagement have over the establishment and development of the CIA?

Bakul Patel: I will take that question. And then we'll turn it over to Jesse and others to sort of comment on and I think. Thank you for the question.

We I mean, the fact that we have EMA represented, and then we have Ray, and Nilay from ML. We're truly wanting to make sure that, you know, of course, the Center of Excellence is not going to do again, everything under the sun.

But I think it's going to start finding things that we need to need to connect to. We need to make sure we are aware of those efforts. We need to make sure the needs that we are seeing the center of excellence will see from other stakeholders are shared with others as well. And that's how we envision this moving forward.

And I know many other many other aspects of how we collaborate. Jesse and I sit on a roll team for AI and machine learning at Xavier Institute, and I think those avenues are the best avenues for us to sit around the table and actually share exchanges and make sure our experiences the means that we are hearing on one hand is shared to the other hands as well.

So that's how I would envision going forward. So Jesse and Amy do you guys want to add.

Jesse Ehrenfeld: I'd be happy. Thanks so much. It’s a great question. I'd be happy to jump in.

Certainly, you know, we've really appreciated the openness that you know, the FDA has had throughout this process to discuss the space and bring the AMA and other physician stakeholders into the conversation. I think that's really important for a lot of reasons.

You know, we need transparency we need confidence in the process, and ultimately, competence in the technologies of products are coming to the marketplace, otherwise, we will be undermining what comes out. And it will

limit clinical adoption, which is what we don't want. You know, we've learned some hard lessons through sort of EHR adoption, when we haven't been able to communicate when there have been problems.

And I think that you all been taking a really helpful approach in terms of bringing stakeholders like the physician community into the fold.

Amy Abernethy: And, you know, I would add that in addition to making sure that we have solid communication channels and will you have thought about who might be missing that we need to reach out to, we need to keep in mind two elements.

One is, we need to build the regulatory science side, as well as the regulatory know how around issues such as user centered design and making sure that digital Health Solutions meet the needs of the people that they're intended to help in the first place.

And then the second is that we really need to build into all of our thinking at all times the importance of inclusion. So digital health solutions need to be available for all and what is that going to take. And so that means that we need to be under understanding as much as possible issues around internet access and access to solutions.

We need to be building into our thinking concerns around bias and understanding how that may impact the development of products. We also need to understand how do different digital health products either help make healthcare more inclusive or do damage by making healthcare more exclusive.

And these are kind of key to actually how we make sure that patients and providers are sort of central to our focus.

Bakul Patel: Great discussion, guys, let's move on to our next topic, which is collaboration.

And I wanted to start off with just laying out I've been we talked a lot about goals and outcomes. And I think there's a lot of excitement in the center of excellence.

Phil also heard where we can be working on, but maybe let's talk about how we should be working on.

And maybe I'll start with you, Amy, is, you know, we all know, collaboration is key, right? I mean, we already know, I mean, you touched upon this is we need to keep the right balance in mind.

You know, what can we do? What can the agency do to facilitate where the channels of communication? And I think, I think in addition to the challenge of communication, I think the knowledge sharing part, can you talk about that a little bit?

Amy Abernethy: Sure.

You know, to start with, we need to celebrate opportunities like this and keep doing more of them. So let's make sure that as the digital health center for excellence, and as FDA, we are keeping communication channels open through listening sessions through public meetings, through dockets. But you know, also through hearing in these sessions, what are additional channels, building public private partnerships, and the things that we've got in our FDA toolbox, but it's sort of also in our community toolbox to do that.

Second thing I would say is that, by the way, one of the elements of COVID is it's taught us a lot about what we're capable of, and what works. And one of

the places I think it's taught us a lot about our capabilities as it relates to collaboration. Because of COVID, we've had to figure out how do we develop safe spaces, to collaborate across all the different actors, inclusive of government, NGOs, academic researchers, healthcare organizations, as well as not only industry from the device and pharmaceutical industry side, but also industry, from the tech industry side of the data industry side.

And finding ways to collaborate and learn from each other quickly, to make sure that new partnerships are built and we understand where the direction of the innovation science has been really, really important.

And over all of this should always be our central focus on collaboration, not only with the patient advocacy community, but the basically society at large so that we're making sure we're pushing forward critical conversations, such as the conversation around privacy that I think Jesse you mentioned earlier, et cetera because that's the other part of collaboration is understanding what are the societal conversations that are critical here.

So my kind of sum total here is do more of what you're already doing.

Learn from COVID and then make sure that as we do this, we chart the path towards new places that we need to have conversations, such as conversations around privacy or bias for the future that are going to inform our work.

Jesse Ehrenfeld: Yes and, you know, I would just add two things to what you just said. Namely, one is, you know, we just had a patient engagement Advisory Committee a couple of weeks ago, I think patients are also one of the key players in this game, I think I would also say education institution, are also going to be a key player into this in this ecosystem.

And I truly mean, don't just mean the healthcare providers, education institution, but I'm talking about technology, institutions as well, I'm talking about other science related educating institution, that's really the sort of the thing that's happening with digital health is that they're getting solutions from all walks of life.

And I think we need to sort of make sure that that we are all starting off with a great, you know, step forward, and how we sort of do that.

Bakul Patel: What - maybe I'll ask the question to Nilay, Leslie, and Rob is, you know, what topics that come to your guys' mind that would benefit the digital health technologies in the short term in the long run?

Maybe you can give us a couple of examples.

Nilay do you want to start first?

Nilay Shah: Yes, sure.

Again, I think this is a really broad area. So you could pick a variety of different topics. I think the three topics that sort of occurred to me were there might be a lot of opportunity, at least in the short term, but probably a lot of it for the long term as well.

One is thinking about digital endpoints. And there's a lot of work going on in this space and parallel across a number of different organizations, be it in clinical organizations, academia, as well as regulatory organizations. And is there a way to sort of collaborate to create some standards around endpoints for via specific conditions or collate them so that can be used in a standardized way, as we continue to grow digital approaches, instead of reinventing things.

So, I think collaboration and collaborating with various groups on digital endpoints would be really beneficial. I think the other piece that you brought, but also a number of other folks that brought up is how to engage patients in terms of how their data are used, what role they play in developing these technologies. There's a lot of challenges right now, as the data reside in various silos, right.

So if we can get the patient to sort of own their own data, be more engaged in the development of technologies. And also to think about, which are the outcomes from the technologies that matter to them. I think there's a lot of benefit and sort of thinking about sort of building on the workshop you already had a couple weeks ago.

And then the last piece is sort of how do we evaluate these technologies? What are what is success? So as more and more of these technologies make goals for FDA approval, you know, what is the competitor on? How do you decide that, for example, a diagnostic approach may have a significant number of false positives, but also may increase the number of patients diagnosed by let's say, half a percent or something.

Is that good enough for, you know, regulatory approval? So what are the approaches? Where do we need randomized trials versus real world evidence in terms of regulatory great approvals?

But also, what does that success look like? I think there's a lot of work there in that space that can be coordinated through collaboration with digital health care.

Bakul Patel: Great thanks, Nilay.

Leslie?

Leslie Saxon: Yes, I mean, I think there's so much opportunity building off Amy's comments about inclusion, because digital really does democratize. And you always have to get rid of this sort of more paternalistic medical model, because there's a great opportunity to include all sorts of people, under resourced people, racial bias in health care, all sorts of disparities can be rectified by digital health solutions.

If you look at even in the context of COVID-19, who's impacted, we need to provide new solutions and gain understanding on how to address the needs of the under resourced, often disproportionally impacted by things like COVID-19. This is the topic of a lot of research we've done over the last 15 years in digital health.

I mean, I've been very surprised you think things like iPhones are sometimes considered rarefied devices of the elite? Well, turns out at our large, urban hospital that serves an under resourced, largely non-English speaking population, iPhones are very prevalent. How can you use sensors, iPhones to understand even the natural history of COVID-19 by building solutions that include people who are excluded largely economically or culturally isolated from healthcare.

And I think the opportunities there are so enormous to really gain understanding as to why are the outcomes worse? To answer questions like what the natural history of this disease a patient sent home on supplemental oxygen or from the hospital or the ER?

So I look at this with humility and I think we have to definitely not think about it paternalistically and we need to think about it as new discovery that involves the patient with digital solutions.

We also have to better leverage technology companies and social media platforms, that have millions and millions of people on engaged for non-health reasons on these platforms. They know how to engage, whether it's a social media platform or another platform. We can learn lessons from them to improve digital healthcare outcomes

Now, these same companies not always responsible in every aspect of their businesses. But there are things they know that are really relevant healthcare.

And there are mistakes that we don't want to repeat. So in our research, we try to reach out to those groups a lot and gain their wisdom The COE should also do this.

Bakul Patel: Great, thanks, Leslie.

Before I go to rob, I just want to remind folks that please put your comments in the chat window so we can address them when to go open lines.

Rob, do you want to take this question about what are the topics that you think?

Rob Kowalski: Yes, if you would have come to me right after Nilay, I think I would have said ditto. Because I think those are a lot of the issues that we're certainly beginning to really work through or have been trying to work through as a regulated industry.

And, you know, I think Amy hit the COVID example, very nicely, which is, you know, and I'll use this to expand on my comments, many of us were trying to move forward and do decentralized clinical trials or patient center, remote trials, where we did, you know, remote visits, and allowed patients to be at their homes, and did virtual site assessments and all those sorts of good things.

And COVID just showed us that we could do it when we really had to. And I think for a lot of these other areas, some of these digital health technologies, some of the adjacent industries that are really getting into the regulated industry for the first time with some of their tools, right? I think we it feels in many of these cases, we're right on the edge of be able to kind of, you know, crack the nut and move forward.

But it will take a bit of glue or a convergence to get those pieces to align. And so maybe like COVID helped us really align quickly around decentralized trials, for example, I think the agency and the COE could play a really great role in trying to push some of that collaboration forward.

And as I mentioned, in my earlier comments, the collaboration here is really the agency, the industry, academics, patients. And I think we can't forget, you know, some of the tech industry now that is getting into this area for the first time. And so, you know, I think when we're right at the edge of being able to do some of this stuff, sometimes we just need a little push or a little bit of glue to pull all the pieces together and get over that hump of can we do it too?

Yes, we can do it. And so I think it feels like we're really kind of at the edge of that precipice looking down.

And once we get through some of those, when we have a couple really good examples under our belt of, we're able to transform a true digital health endpoint, for example, then I think the others come easier. The first ones are always the hardest. And maybe there's a bit of a push that we can all do together to kind of, you know, break through that barrier, if you will.

Jesse Ehrenfeld: Yes, I just want to remind people of one thing, thing, if you have not seen this, HHS, the Health and Human Services is actually holding a designer-a-thon. It's going to kick off on November 16 that talks about the goal of that designer-a-thon is to make sure that COVID-19 (unintelligible) anywhere diagnostic, can be loved and inviting all stakeholders to come the technology is developers, designers, engineers, et cetera to come in and come up with a solution that, you know, that really takes the COVID-19 diagnostics, into the into the fold and try to come up with some innovative solution.

So I just wanted to make sure that no people understood and I think this falls right in line within a - Rob, what you were just saying.

We need to sort of make sure that these things happen on a regular basis. And let me just go to sort of the mechanism of before I go to the mechanism of how do we collaborate.

Maybe Ray and Jesse, you can sort of give us know from your perspective what are the lowest hanging fruit? What are the best things that we can sort of engage in to advance the digital health technologies field?

Ray Dorsey: So I'll give for and I just want to echo delay Leslie and Rob last comments, especially about covert being a forcing mechanism and what's necessary to make that force mechanism permanent, I think will be policy changes.

Now, I'm a little concerned that if we get a great vaccine for COVID -- fantastic -- but that telemedicine will disappear in the absence of a permanent policy changes and that people will go to what was before. And what was before was an inaccessible healthcare system, that many individuals that was centered on institution and not on patient.

So I think there are four big things that could be done.

One is decentralized central trials. Rob already highlighted that the forcing mechanism that led pharma to do it realize if it is possible that we can be more inclusive, we can be more participant centered. I think FDA should continue to provide policies and support for that direction is more inclusive, as Amy indicated.

Second is that we better measure the disease. And Leslie was talking about this. We have computers around us, wherever we go. They can measure our health in the past three days. And those (unintelligible) better endpoints that we can evaluate new therapies in a faster, more streamlined way and accelerate the development of new drugs and devices for a lot of the underserved conditions.

And then we need to make these therapies more accessible again because, you know, these things are held by lots of people. More people have these than they do have refrigerators and shoes around the world. And I think the fact that we have very, very, very powerful ways of measuring health, and potentially very, very, very powerful way sort of delivering healthcare, the FDA, and more broadly, policymakers should be accelerating policies that facilitate our adoption.

Jesse Ehrenfeld: So I think I'll just add one quick thing, because I think we've already had a great discussion.

But you know, just as there have been opportunities for other stakeholders to be involved further upstream in the review process, I think it's important for both physicians and patients as well, so that we know what to expect, what do we need to be comfortable when a device is released, and I think that could be really, really helpful.

You know, the reason that so many people have these devices is because they see the value, and they understand and prioritize it. And I think the degree that we can get more stakeholders involved further upstream, that will benefit adoption overall, as there's more trust and transparency.

Bakul Patel: Great, thank you, Jesse.

Operator, can we just open up the lines and get some comments from the audience?

And while that's happening, I'll just pose a question to Ray and say, you know, what do you think is the best mechanism to the points you just raised about them working on DHTS that you think would be best suited? Of course, the bandwidth of SGA is not finite. So we have to figure out how to do this.

What would be here be your ideas?

Ray Dorsey: I think people love examples. And people get - someone asked me today, when I give a talk to a pharmaceutical company on the very same topic, can you give me an example of a drug that was approved using a digital endpoint and I couldn't.

Maybe someone here can. I think if these things are actually demonstrating, I mentioned the first approval of digital therapeutics, when you get an example that really makes things real, and you pioneer software as a medical device, and you start approving people under precertification or entities around a precertification program, that's extremely valuable that people can then use that as a guide to their own internal assets.

Bakul Patel: Great. Operator, do we have anybody?

I'm sorry, go ahead.

Ray Dorsey: I was asking if there's been a drug approved on a digital endpoint. I'd love to know.

Bakul Patel: Rob, do you want to respond to anything? Or Amy? Yes.

Amy Abernethy: I actually wanted to just expand a little bit on what Ray was saying, which is that - and I'm not going to specifically talk about any drugs that were approved on my additional points, just so you know.

But you know, as we are in the context of COVID, and we've seen the demand of decentralization in a number of ways, as FDA, we put out a public health emergency guidance that highlighted the ability to use remote patient evaluations through telehealth, the understanding of the role of digital evaluation through remote sensors, even the ability to deliver investigational product to patients homes or nearby physicians.

As these capabilities have been leveraged for clinical trials for COVID, it gives us a really important opportunity that I think follows on what Ray has

been saying, which is to stop and take stock of how did those solutions perform.

So we think of a decentralized clinical trials and really a critical way of making clinical trials easier for patients and improving access for patients. Importantly, we worried about some of these solutions because we worried about the impact on patient safety as well as the integrity of the data set. So it's important to stop and measure.

You know, what is the impact on patient safety and integrity data set and demonstrate how this has really been a very important set of capabilities that have been leveraged and we can understand (unintelligible) COVID.

And so I think in line with your point about use cases, Ray, actually - not only are there sort of the opportunity for use cases, but there's the opportunity to do detailed intentional learning, which will help push the whole space forward.

Bakul Patel: Agree with you.

Operator are there any callers to make some comments?

Coordinator: We have one from (Jesse Lin Van). Your line is open.

(Jesse Lin Van): Sure, thanks. This is (Jesse Lin Ven) from Duke University's.

And I guess I do want to also say thank you for holding this sort of open session. It's really great to have the opportunity to hear all about this.

And one of the areas that we're really interested in is understanding who is expected to be responsible for aggregating the evidence for verification and

validation of tools that collect digital data and more specifically, thinking about those tools that may not have been initially designed for digital health purposes. So thinking more like smartwatches, and smartphones and things that are marketed more towards the general public, so in terms of avenues generation, that we're thinking like pharma companies, device companies, or independent research labs, for some examples.

Bakul Patel: Yes, anyone want to take it.

Jesse Ehrenfeld: You know, what, let me make a comment that maybe doesn't address that exactly. But it's been on my mind.

Getting collaboration, right, and sort of figuring out those responsibilities is important.

And there was a comment earlier about collaboration between the center and CMS, thinking about coverage and payment, it's really important that that happens in a way that works, because otherwise, we're going to get burdens that crop up downstream.

And we've been in situations in the past where you have regulatory review that occurs, but then when you get to the payment and coverage side, it becomes infinitely more burdensome, when you've got a new evolving and potentially costly technology.

And so I think all parties have a really strong incentive, including payers to collaborate to get this right. Otherwise, we could end up with a lack of clarity, where we end up with a mess, where you've got payers having different levels of evidence to enact payment that then just prevents the marketplace from getting access to these new products.

Leslie Saxon: Yes, this is Leslie and I would say to the researcher in the same way that the markets are not mature, and the payment as was just referencing, if you're doing digital health research and you're increasingly aware of the fact that commercial centers, commercial devices, have medical grade sensors, and they have an incredibly important role to play on the diagnostic side and maybe apps on the identification of digital therapeutics, it's kind of hard to get research funded now. Because that's untraditional research in that area.

So it's a great challenge. But the opportunity to make really seminal discovery, I think is there and then to, to leverage the patient their own care.

So I encourage the research, I think it's enormously important, because we'll get to those answers.

Amy's talking about, you know, that sense of (unintelligible) that this stuff, in fact, has added value and included more people and such, but it's not that easy to get it done because traditional funding sources largely haven't recognized it as a research area.

Bakul Patel: Great. So I have a question on the chat window, which talks to - and I'll paraphrase it a little bit.

I think one of the key issues with digital health technologies is that technology moves so fast. By the time we do research and validated. And the technologies are already at like version five from where they were when we first started.

I think that's sort of goes back to the point you all made about, you know, constantly learning constantly trying to see what's important. And as we start

incorporating this, you know, and somewhat less expensive technology then will be used to sort of incorporate into trials. How do we sort of think about it? So I think that's a nice next question towards - in this learning system that we are trying to get towards from a regulatory perspective.

But also there is a research angle to this and saying, you know, how can the research be more nimble? How can standardization, you know, and then talking about technology standardization, maybe there are other sets of standardization can be more nimble, that recognizes the currency of the state of technology.

Folks want to comment on that?

Ray Dorsey: I can maybe try to take a stab on some of this.

And I think, as we're thinking through this, one of the things that we're trying to keep a very open mind and we should is not trying to solve down to the minute detail but to actually solve for it -- framework that's adaptable.

So in the question, the chat, for example, you know, how do you reconcile a continuous data stream of safety information, right, you're going to have to be able to apply some sort of AI or ML to pull out a signal that matters versus a patient just rustling around and that's not the same as a fall.

So how do you reconcile that entire data stream? We don't want to have to do that a million hundred different times for different diseases and filing different devices, we want to come up with a framework that looks at the basic principles of what you should be doing to make sure you collect the right stuff and ensure patient safety.

And so in all of this stuff, as we're, you know, trying to engage in and have these discussions is to try to be at a high enough level that you can then establish, as I was saying, a framework. But then you can apply it even as the technology changes.

Because, you know, we're starting to think out already. I mean, you know, the industry and the agency already negotiating produces seven, which takes us out into the middle beyond the middle of this decade, we can't first second begin to imagine what technology we're going to be working on in 2027, let alone 2022, in some cases, and so we have to approach this in a very flexible way.

But we still have to try to define it at some level. So there's a balance that I think we're trying to figure out as we go into this to stay open and nimble enough that, that we're not locking ourselves into something that becomes obsolete as soon as it's, it's codified.

Yes, I think that's raises a really good point about staying current in skills and knowledge and technology and people focusing time on saying that current and having that currency is going to be extremely important, not just for FDA, but everybody in this community or for the end users of the technology.

Bakul Patel: Operator, can we go to the next caller?

Coordinator: The next color is (Michelle Ruben Owner). Your line is open.

(Michelle Ruben Owner): Hello, thank you so much. Can you hear me?

Bakul Patel: Yes.

(Michelle Ruben Owner): Perfect. So my question is actually reflect a little bit the previous discussion that we were having regarding the role of the center to kind of train everyone from FDA to industry, to DMS to Congress and everyone and I was asking you, what I want to know is how you envision training, FDA, the entire CDRH, all the different branches, about new clinical guidelines relating to digital health, or the revolving regulations regarding machine learning or artificial intelligence, to ensure consistency among all reviewers.

Bakul Patel: First of all, I don't think this year is going to be a training center for everybody in the world, I think it's going to be a unreachable goal for, for the Center of Excellence, I think we can become that need spotter, slash providing the expertise that we have in the center of excellence, to make sure that the needs are aligned, and then connecting them with the right skill set. and making sure that that transparency and the knowledge sharing happens. And that's one of the goals of the of the Center of Excellence.

So I don't want to be an overly misleading to sort of talk about yes, we'll be training everybody. But I think we're going to share knowledge. As we start moving forward. I think part of sharing knowledge will be sometimes training, but not all the time.

(Michelle Ruben Owner): Thank you.

Bakul Patel: Next, can you go to the next caller.

Coordinator: It's from (Anne Weyland). Your line is open.

(Anne Weyland): Hi, thanks, everyone for a tremendous discussion.

I was just wondering, I'm probably following up on the last question. I mean, worldwide, there's such a lack of device harmonization and device regulation, and an outlook on what even is a medical device and no causes. It's much enough difficulty when you're talking about standard medical devices. But this takes it to a whole new realm.

So just wondering like, worldwide, is there plans for discussion or to bring other health authorities or notified bodies into the center of excellence to discuss potential harmonization standards and regulations for this areas specifically for digital health? I didn't feel like it'll particularly helpful when we're talking about deployment in clinical trials.

Bakul Patel: Yes, it's a great question and how I see two or three areas that are where international collaboration makes a lot more sense, right. One from the medical device space. We have been very much engaged with the international medical devices regulators forum that's been sort of instrumental in in putting out the framework like Rob was talking about for software as a medical device.

As we are leading as an as an agency, in trying to solve some of these challenges, other regulators are also facing the same sort of aspects. And I think there's that forum provides a really great opportunity for all regulators to learn from each other. In fact, we have, we have already worked on topics such as cyber security. And now you're continually continuing to embark on this space of artificial intelligence and machine learning and defining recovery.

So I'm going to stop there. But I think there's opportunities that we also engage, not necessarily all international aspects, but the standards in industry

led standards organizations are really key to one of the instruments that we use in our regulatory standards expectation setting to sort of work.

And I would also like to hear from Jesse and Ray and Nilay and see if you guys see from an clinical perspective, are there opportunities that can sort of bring these two, bring the worlds together?

Jesse, do you want to go up any time soon?

Jesse Ehrenfeld: Sure. I think there are a lot of opportunities in the US, you talked about sort of the regulatory side, what's happening in NDRF.

You know, we've been watching what's going on and the sort of standard setting arena between anti (aimia) BSI, FDA, I think there's those are all really, really productive things.

But I think there's a lot of opportunity, when I think about kind of the medical community to sort of come together, we think about where can we collaborate so that we can help make sure that we've got a shared framework that makes sense, so that we can again, help accelerate adoption out the marketplace.

Bakul Patel: Yes. Amy, or Nilay do you have any thoughts and collaboration we do, or should do?

Amy Abernethy: This is Amy. You know, I don't have anything further that than what you were discussing before I was, was thinking about the opportunity to develop better standards, for example, for AI, and harmonization of those standards will be helpful over time. But you know, I think a lot of that work is underway.

Nilay Shah: Yes. I'll just add, but yes, this is where an opportunity for digital health care could be to sort of help coordinate that, because I think one of the challenges is also potentially a lot of different groups coming up with different frameworks. So how do we sort of keep some coordination?

So there's a single approach through which people are working, I think there's a little bit of a challenge right now, just because of how quickly this area is growing and moving.

Bakul Patel: Well, I think we're coming to an end here who's bound discussion. And I know, I want to take this moment to thank you all on the panel into sort of taking the time out of the day to come join this conversation. I think it's really great for the Center of Excellence to learn. But I think, I think it's also important for us to engage with you all. So I'm really, really thankful.

I'm going to summarize really quickly what I heard and then turn it back over to Irene and thank you, all the people that are dialed in today, to listening in to this listening session.

I just want to reflect on -and I'm really, really excited to sort of hear that we - I heard an ongoing Clark clarity call that we can work on and I think very much aligned to our goals - learning regulatory system that goes back to our goals on the how to innovate regulatory perspective-wise. I think education and standardization is one of the key things walking away with.

And, you know, I think collaborating with others, but not overstretching ourselves was another team I heard that will sort of move us forward. And I think working with example base -- I think Ray sort of hit upon this and Leslie talked about this as well -- is being clear and how the center of excellence

goes going to contribute to the work that's already happening is going to be one of the key sort of success areas.

So I really thank you all for providing this insight.

And I think the callers especially sort of raising these questions are great -- really, really helpful.

I'm going to pass it over to Irene to close the call.

But again, thank you again, everybody, and thanks for being on the call with me.

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 webpage at www.fda.gov/training/cdrhlearn by Friday, November 20.

If you have additional questions about today's discussion, please use the contact information 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. The survey can be found www.fda.gov/cdrhwebinar immediately following the conclusion of today's live discussion.

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

Coordinator: This does conclude today's conference call. We thank you all for participating.

You may now disconnect and have a great rest of your day.

END