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Gregory Daniel: Today's presentation is made possible through a cooperative agreement between the Duke Margolis Center for Health Policy and the FDA. Statements made today do not necessarily reflect the official agency position for policy. Our working group members are likewise reflecting their own opinions and not necessarily the opinions of the organizations by which they're employed.

Working Group Members, as you can see on the slide, we have a wonderful group of senior leaders in mHealth, across a range of perspectives. I want to say how excited we are to be working with this great group. As you can see, we have recruited a diverse set of opinion and thought leaders in this space and we look forward to working with these experts in mHealth and in real world evidence as they are primary drivers in helping us to craft recommendations for strategic next steps to improve mHealth as a tool for evidence generation and evaluation going forward.

Several of the Working Group Members will be presenting on material today. Starting with Greg Pappas from the FDA, Ravi Ramachandran from PatientsLikeMe, Mo Kushal from Stanford, Seth Clancy from Edwards Lifesciences and Megan Doerr from Sage Bionetworks. Just to go over briefly the agenda for today. There's a bit of an overview of our webinar, we'll primarily be focusing on addressing stakeholder engagement, needs and incentives. We'll also be proposing a way of putting mHealth data into types of buckets, to address some of the issues that differ between these different types. We will end by going over the Work Group's next steps and going over information about the public comments period that will follow this webinar.

So, with that, let's begin with the project scope and goal of the webinar. Given the level of excitement that we've seen around this particular topic, I think it's fair to say that we're at a pivotal inflection point in the availability and usability of mHealth apps and wearables. This technology enables patients to take control of their own health in healthcare.

We can see these technologies as an increasingly important source of real world data going forward. This is especially true in the context of medical devices, where efficient collection of long-term data is a critical component of the evaluation and survey-als. Because of this the National Evaluation System for health Technology, or NEST, is uniquely positioned to make use of this innovative source of real world data.

As mentioned by FDA commissioner Scott Gottlieb in his blog post about digital health last week, as well as to be involved in a development and dissemination of analytical tools needed to transform this data into actionable knowledge. You may have seen in the Washington Wall Street Journal article published just today, talking about cell phone based research, potentially making it easier to recruit, conduct and monitor large populations of patients for research studies.

Before diving further into this topic of the day, I want to stress the importance of

mHealth as it relates to the broader learning healthcare system. In roughly the past 10 years we've all seen an explosive growth in both the cost and complexity of healthcare. This has shined a spotlight on the need for real world evidence developments that could inform and improve innovation, care and value. As such, there has been a world-wide movement to include the voice of patients in medical products that are researched, developed, marketed and used. However, many of the sources of real world data that exist today are less than optimal, or don't adequately represent patient priorities or their perspectives.

New innovative products being introduced in the market with the ability to treat or cure medical conditions, while at the same time consumer wellness and health technology, are proliferating and becoming more advanced. As these promising technologies and methods advance the vision of the learning healthcare system, we must also make sure that our policy and research institutions do as well. In this vein, mobile health or mHealth, is an excellent example of the challenges and opportunities represented by the next generation of evidence development platforms.

mHealth promises to further impower patients to participate in their own healthcare, while confronting us with a complex, big data, operating environment where regulations, standards and best practices are still being discussed. A key to harnessing these data to improve the lives of patients and making sure that the necessary infrastructure incentives are in place to encourage the generation of real world evidence from these data, that can inform better care for people.

Systems like NEST will be central to national efforts of linking data, people and policies toward real world evidence generation by leveraging strategic partnerships, critical data resources and expert opinions to establish a more accessible and reliable infrastructure to conduct analysis, including mHealth. It is with this backdrop of these developments that we have approached the topic here today.

In terms of our projects scope, the project that we're talking about today will hopefully be a valuable step toward understanding the opportunities and challenges in collecting data from patients about their experiences and symptoms, as well as objective data about patients abilities and their capacity to conduct activities of daily life. Historically medical studies have incorporated patient reported outcome measures and performance outcome measures as part of clinical outcome assessments.

In recent years FDA and other players in the medical ecosystem have started putting more emphasis on understanding what outcomes are of most importance to patients, as well as understanding what is meaningful change to patients. For example, you may have a sleeping aid that statistically proven to allow generally healthy people to sleep an extra three minutes a night and while that might be a useful, most people three minutes would not be a meaningful change. Because of the explosion of mHealth technology, there's an opportunity to use this data to start to take novel measurements in quality of life and people's ability to conduct

the activities of daily living.

There are also opportunities to understand what is happening with people in between their interactions with healthcare providers. Most often patients spend most of their life outside of the healthcare system and having ability to better collect these data during their normal daily lives would be very helpful. It's easy to see how this data could be used by people and their doctors to manage their health. There are a lot of technology companies entering the space to do so.

This project is focused on, if and how, the data generated by these technologies, designed for personal and clinical use, can also be used for real world evidence generation. As part of that we'll need to address questions surrounding the accuracy and reliability of the data based on particular uses. Best practices to keep people engaged in sustained longitudinal data collection, as well as efficient linking to other types of data needed for evidence development.

Just want to mention that outside of the scope of what we're talking about is evaluated mHealth technology as medical devices themselves. Some types of mHealth technology that produce data could be useful from medical product evaluations may be medical devices themselves, such as glucometers. Other mHealth technologies that resides outside of the scope of FDA's definition of a regulated medical device may also be useful, such as pedometers, FitBit's, et cetera.

Our work will include recommendations around both types of technologies. With that said, we have heard from multiple sources that companies are concerned that if their devices are used in medical research this may cause their device to be regulated. There's a very nice decision tree style tool, provided by the FTC, that can be used to understand what FDA, FTC or OCR laws may apply to your device.

That said, I am now going to hand things over to Christina Silcox, a research associate here at the Duke Margolis Center, for a quick synopsis of some of the work of organizations like ONC and Accenture, and what they've been doing on the future of mHealth and patient generated health data, and how that fits into our vision of using mHealth data for evidence generation. So with that, I'll turn things over to Christina.

Christina Silco: So ONC and Accenture, recently released a draft framework on what they thought the patient generated health data will look like in 2024. So we decided to start with their example of "Christie", who's a typical 38 year old woman, she has a history of high blood pressure. In between her annual exam she used mHealth technology to track multiple aspects of her health. This allowed software that she's given permission to, to make recommendations to both her and her care team about healthy changes she could make, or how to deal with sudden changes that may affect her health.

But, how does this software know what recommendations to make? This is where the learning healthcare system comes in. While the weight, steps and blood

pressure tracker collect important individual data about Christie, it can also be collected for evidence generation that allows individualized, shared decision making. The same type of evidence generation can be used to continuously evaluate the benefits and risks in medical products and treatments.

So in 2024, this data collection is second nature to Christie. In fact, there's a good possibility that these trackers are embedded in her clothing, home and phone, and so she collects this data with essentially no changes in her normal routine. Despite this invisible data collection, Christie has control of who she shares this data with, and what data about her can be [inaudible 10:27]. She can both authorize and revoke access any time and these types of centralized apps make recruitment and informed consent a much more efficient process.

Because there is this expectation that mHealth will be able to link to these sort of centralized apps and used to provide actual information for the users, mHealth developers must provide information about the accuracy and reliability of data coming from their devices for their target applications. Standards have been set through consumer technology associations, as well as devices that are medical devices, have submitted data to FDA for clearance and approvals. This facilitates this sort of recommendation making.

It is common and expected to use standardized API's to push and pull data, along with specific information about the hardware and software versions, to and from these centralized data bases, based on the user permissions. This is because the market remains fragmented due to continued innovation. Raw data from accelerators, gyroscopes, et cetera, are also sent so that data analysis software can use common algorithms when they're combining data from different devices.

So now I'm going to move ... I'm going to pass the presentation along to Greg Pappas, who will talk about how this kind of information is going to be used to leverage real world evidence. Greg?

Greg Pappas: Hi. Hi everyone. Thanks Greg and to Christina for framing this in a nice way. This is, kind of, an increasing level of refinement. I just want to put a little bit finer point on the distinction between mHealth as a mobile medical device, something that's regulated by the FDA, that is involved with the diagnosis, treatment, prognosis of the other things that we consider to be medical devices. There are, of course, software currently, and some of them that are deployed in apps that are already medical devices.

Let's leave those aside, an important category, but what we're really focusing on here is how mobile apps could be used as part of evidence that can be used to evaluate medical devices. Of course, medical devices of all types. The focus here, obviously, is on NEST, the National Evaluation System for health Technology. This is an emerging system for evidence generation of medical devices. We are building on the reality that increasingly digital information is available coming out of real world, what we call real world evidence, coming out of routine clinical care that we have been using and will increasingly use in the future to evaluate devices.

So NEST is not a device, it's not an mHealth environment, it's an evidence generation system at large. Currently we've been using registries, EHR's, claims data in novel ways to produce evidence that, I think we can say now safely, it's better, faster and cheaper. That's, kind of, my mantra for NEST. We're not doing evidence generation in NEST because it's cool, it is cool, but it's because we believe that we can do what we need to do, that is evaluate medical devices regarding their safety and their efficacy in ways that are more efficient.

In the same way other users ... The same data ... If we're using the same data other stakeholders can more efficiently meet other needs. Help health insurance companies, the payers, hospital systems, all have needs for the same data around the evaluation of devices. Now, with that said, with the focus on device evaluation and evidence, the issue is being raised in this stream of work with an action plan about how mHealth can help or enhance medical device evaluation to help build the NEST, as we understand it.

Currently we're using some mHealth applications to link and augment other data systems to evaluate the devices. We're going to get into some of those prototype examples, those proof and concept examples. I think all of us working device evaluation understand, that standing alone, that none of these data systems really can do too much. It's really when they are linked with one another that the real power of the data really shows through.

So, with that, I think I've pretty much run out of my time and I'll turn it back to Christina to move us forward.

Heather Colvin: Thank you very much Greg. This is Heather Colvin. I'm the project director at Duke Margolis. So, when we initiated this project with that scope of work, the key thing that we were really interested in is, okay, well we have this ideal vision of what we want it to look like in 2024. How do we get there from where we are now? So, we asked some pretty simple questions. You know, what are the different types of mHealth data that are out there currently, or that we envision to be out there? Are there things that mHealth developers are already doing, or could be doing, that would be reasonable in the short term that we could start using the data that's produced by these devices and technologies earlier on?

Some of the questions that we come up with are, what are the challenges that are impeding any progress in this area? One of the key factors that we keep coming back to is, what are the key things that make people initiate the use of the technology, and sustain use of that technology, over extended periods of time that would enable us to have a longitudinal look at their activities of daily living that might be incorporated into this broader evidence generation approach? Then we are looking at, so, how do we then marry these two things with what's actually happening in mHealth technologies out there? How we encourage people to use this technology, with how these then stick with the larger research communities needs?

So, these are the types of questions that we've been asking amongst the working group over the course of the last couple of months. So, we've broken down what we think the action plan will need to address. We're going to be talking about a variety of these pieces on the call today. A lot of this is, how do we use this to contribute to real world evidence generation? What are the types of primary issues we face in user engagement that also look at researchers needs and the needs of different sponsors of research? Then also, what are the incentives for these companies to, maybe, adopt different approaches that would allow the data that they're generating in their devices to be appropriate for this type of activity?

We also intend to, over the next month or so, also include a broader set of activities that are, kind of, outside the scope of this project, but we think our pertinent that really address some of the larger challenges to digital health more broadly. Some of these are, how do we appropriately address issues of informed consent? It's one thing for a consumer to pick up a product and start using it, but how do we make sure that they are aware, or agree to their data being used for research purposes or broader evidence generating activities?

What are some of the key issues that we face in then linking the data from those devices in technologies to the types of registries that Greg Pappas was speaking about? Then one of the things that we hear a lot is, kind of, the diversity of the technology out there. What are the issues that we face when we're looking at a diverse, fragmented marketplace that is driven by innovation, and constant competition and change? Those are good things, but how do we address that in terms of how we make the data appropriate for research.

Then the broader issue of, what do we mean by "fit-for-purpose"? It's really, kind of, a case of it depends on what the data is and what it's being used for, but we wanted to have some broad based discussion about what we meant by "fit-for-purpose". However, we're not going to be able to go over all of the work we've done so far in this webinar, so we're going to focus on these key topics; the recommendations for user and research engagement, identifying the different types of data types.

So on the agenda today, we're going to have a series of Working Group Members presenting. They're spread all over the country, so we are dealing, we're using technology to bring us all together. So you might feel a couple of glitches as we pass the buck from one presenter to the other, but I think that each of these Working Group Members represents a particular stakeholder group and perspective.

So right now we're going to go into the issues around addressing the needs to build engagement more broadly. We are going to have an opportunity at the end of this section, we're going to have three presentations. Then time set aside for you, the participant, to give us some feedback, either in writing in the question section or we might ask you to speak up on the webinar.

So, thinking about what we think of as the three legs of the issues that we need to

address to make this a viable pathway forward, are the issues of user engagement and health company incentive, and researcher and sponsor needs. To address some of the first issue of user engagement, we have Ravi speaking. Ravi, are you on the phone?

R Ramachandran: Yes I am.

Heather Colvin: Please go ahead.

Christina Silco: Ravi, just so you know, we've had some technical issues and we're going to need you to say, "Next slide", and we'll just move the slides for you.

R Ramachandran: Okay, thank you. Thanks Heather and thank you to the Duke Margolis Center for Health Policy and the FDA for putting this panel together. I'm delighted to be on this panel working with some of my colleagues in pushing this, what I think is a very important area of mHealth, forward. As Heather just mentioned, we are trying to address what is essentially a three legged stool.

One of the issue that I'm using user engagement, in the mHealth space, that would not only enable people to start using the technology, but also to keep them sustained in the use of this technology. So, within the scope of that, then we come to a couple of key issues. What are the characteristics of mHealth app and wearables that actually encourage the sustained usage through time? We do not want to draw up something that has very limited shelf life. We want something that people will incorporate as part of their daily lives so that we can actually now draw up the data sets that are necessary to provide actionable insights, so that people can make decisions about their health and wellness.

So, then that raises the second question, which is, how do we ease this transition from being the user of mHealth into being a research participant so that people are now actually engaged and they're only generating the data. Perhaps also, helping analyze the data in telling us, you know, "Here are the things that I'm really, really interested in, in my own health and wellness journey. What are the tools that, I think, I would need to help me get to what my health goals are in life."

Part of this process therefore, if it moves all of us in the area of mHealth, to make this technology, whether it's apps or wearables, become integrated into every person's life in a sustainable fashion. So, for that ... What this entails is actually listed on this slide. So, how do we cultivate approaches to sustainable usage? Make it easy to use. If I'm going through life, the last thing I want to do is stop and engage with something. If it can be part of accurate user data and living, then that's good. It's easy to use, there's no factions.

Then the second then is, how can we get more information from the use of this app or wearables, so that it imparts people to be in charge of their own wellness? How do we integrate this data then, with clinical management and clinical information tools, such that clinicians will also use this in their shared decision making? So earlier we heard about this learning health system, and what we would like to do

ultimately from going from 2017 to 2024, is how do we make these mHealth tools part of the shared decision making so that people, we the consumers of health or mHealth, are now part of this process and not just consumers?

So, if you want to do that then what we have to, as a group, what we think we need to do is make the design of any of these apps or wearables, person-centered. So start with the end user in mind, then let these tools so that it encourages the sustained usage and it's a [inaudible 25:10]. Then once we solve that, then the other, sort of, issue that comes up is, how do we address key issues of security and privacy?

Other industries like, banks have already done this. You know, so none of us think twice about going to an ATM or using an app on your smartphone to conduct banking transactions. Yet we're not there with regards to our own health, which I would argue in some ways is more critical to our happiness and wellbeing, than making sure that my $50 check is actually credited to my account. So, what to do? We need to have people sufficiently comfortable and are ensured the security and privacy of the data sets.

The last bit is if you want to encourage the sustained user engagement, then we have to draw up a value system. Not only a value system that is personal and meaningful to each person, which is important, where also a value system that encourages altruism, for example. How do we use this data to conjugate for the greater good? We'll get to some of these features later in the next couple of slides.

So, when we, as a group, started thinking about this, we realized, "Okay, there are some features of mHealth apps and wearables that already make them successful." We'll go through some of the examples in the next couple of slides. The next question that came up was, if we think through this process of evidence generation from features that are meant to increase and sustain user engagement and develop value for the users? Are we, in some ways, creating a bias in the system? How do we address that as well?

Then as a group we also want to figure out, what are the recommendations by which we can bridge the transition of user to be active research participant? These are some of the key issues, that this action plan that we want to develop as a group, will need to address.

Can I have the next slide please? So, working for patientslikeme where around the digital health strategy, real world user engagement is something that I live with on a daily basis. Here's a quote from one of our members on the patientslikeme website, which is Cris who lives with ALS, "Without my voice, things would remain in status quo." That's a powerful statement from a member who has ALS, saying, "I want to be part of the system. I want to be part of the solution because without me the system is going to remain the status quo."

We want to have more of the Cris' involved in our journey from 2017 to 2024. The real question is, how do we engage and impart people like Cris to be part of the

solution? There are a couple of other quotes from this paper that Megan Doerr was the lead author on in JMIR, and Megan will talk later about the types of data systems that we hope to capture. In this study a couple of the participants said, "I very much feel like participating because I feel I am helping reach an overall outcome." Again, this person wants to be part of the solution and enable us to push forth, but at the same time, we also have to recognize there are people like, the person in the last quote who says, "I lost interest and/or motivation and stopped recording the data for a while."

So the real question for all of us to think about as we go in the journey from 2017, where we are now, to 2024, is how do we engage more of the Cris' and how do we create an ecosystem that people don't feel like they've lost interest or motivation, but want to be part of the solution again? That is the challenge facing all of us as we think about mHealth and the technologies and how they're useful in going about their daily lives.

If I could have the next slide? Please. So, we're not just going to tell you, "Here are some of the problems.", and "Here's what we'd like to do." What we're actually ... In this slide, which I borrowed from John Reites from Thread Research, who's also part of this Working Group panel, is some of the ways in which we could engage user participation and impartment in this journey forward.

What you see on this graph is an engagement predictor tool that is research developed, where you have two axes. On the one axes is motivation. From very low motivation to very high motivation. The x-axes is friction, going from high friction to low friction. Low friction to high friction. You have on the bottom right is a person that's very low motivation and very high friction, or user engagement. Which results in quotes like we saw in the previous slide, saying, "I stopped recording the data because I did not feel motivated enough."

However, if you now move all the way across the graph to high motivation and very low friction, you have a person that is a very happy, green smiley face. Which means this person is now wanting to be part of the ecosystem and wanting to be part of the solution, a person like Cris, who says, "I want my voice to be heard. I want to be a part of research in moving this journey forward."

So, then what is the motivation factors that encourage people to participate in such research? It could be the clinical benefit that they derive from seeing and acquiring their own data. It could be this altruism concept that we talked about, being a big part of the greater good for society. Could it be that we could make these apps and wearables fun and engaging and enjoyable so people actually feel it as less of a burden and more of a fun activity? Whether it's for entertainment, or maybe even education. If people learn from things while performing a daily task or activity, will that keep them more engaged?

Perhaps the key factor in keeping people motivated and engaged is making sure we collect all of these data passively, and add value to their daily living so that they not only perceive a value, but can actually realize a value for participating. The more

we make these data collection methods active, by which ... What I mean by that is, you know, having people push two or three buttons and tap on multiple screens and have them engage with these things for more than 30 minutes a day, for example.

Then that leads to high friction and a high burden on a person who's already engaged with work/life balance. So the more we can make these tools highly motivating, with a low friction, the more value we'll realize in moving the field from where we are to where we would like to be.

Can I have the next slide please? So then, along this journey, where are we now? So where we are now is people are using a number of tools and devices and apps to collect data. I do that certainly. I have a number of tools that I use to manage my own health and wellness. Are the clinicians who you all want to be part of the shared decision making in the learning health system actually using this data?

So here's a survey from Rajiv Leventhal at the Medical Group Management Association, which was released in June, earlier this year. Where they surveyed over 1,100 clinicians and often when patients come to you with their patient generated health data, be it from a wearable or an app, are you using that in the shared clinical decision making? Only 6% are doing that. 6% out of 1,100 clinicians are currently using person generated health data in clinical decision making. Of that 6%, the majority of the clinicians use this information to set activity goals. Things like, "While you walked 10,000 steps since I last saw you, let me now raise that to 15,000 steps until the time you come back to the next clinic visit."

Even fewer of those 6% are getting data directly from the device that the patient is using. Which means that 81% of the clinicians are not using any data that the patients are generating for clinical decision making. In contrast, if I could have the next slide please? 70% of U.S. adults, in a survey done by Klick Health, also 1,000 U.S. adults, 70% said the technology would personally help them manage and engage in their health better. This is ... It doesn't matter whether you're male or female, whether you're under 20 or over 55, people view technology as a very important tool and resource in helping them stay healthy, better manage their conditions, locate care for their loved ones, help them to prevent sickness or disease and interestingly on an average 14% want to have the physician use this data to provide an early diagnosis. 41% of these, of 1,000 U.S. adults, are using mHealth technology now personally to manage their health.

In the earlier slide we saw 6% of the clinicians using this data, with 40% of the U.S. adults now are already using their devices, or their apps, to manage their health, which means we have a gap. So, could I have the next slide please? This is what we're calling the patient generated, or person generated health data gap. 70% of the people want to use their mHealth data to manage their health, only 6% of the clinicians are using the mHealth data in shared clinical decision making. So there's that gap, so part of our journey in this process moving forward is, how do we solve this, bridge this gap?

Which means we have to do a number of things, and three of them are highlighted here. Solve to the right user needs. Are we solving for the right problem? Are we providing tools and data, and insight and knowledge that are helping the end user, the patients, us. All of us, we're all going to be consumers of health. Are we solving for the right user needs? Second, how do we incentivize mHealth companies who are developing these tools, and who are the second leg of this three-legged stool, how do we incentivize them to develop the right tools to solve the problems for the patients? How do we address the sponsor of perceived clinician barriers that are preventing them from adopting these person generated health data, or mHealth data?

That's the crux of the problem and what we'll see moving forward in this webinar is how is the Working Group thinking around what kinds of data do we need, how do we incentivize the companies and how do we address some of these barriers to adopting person generated health data? With that, I'll hand over the slides to the mHealth company section. Thank you.

Christina Silco: Thank you Ravi. The next person up is going to be Mo Kushal. Mo are you on the line?

Mohit Kushal: I am, good morning. Hopefully everyone can hear me, so a pleasure to be part of the Working Group and thank you everyone for taking the time. So, slide 22 please. The next couple of slides we're going to go into more specifically some of the mHealth company incentives. Importantly what we're trying to think to what incentives are necessary for the companies to actually design their products to have the capability to collect and share the relevant data. Issues that we're thinking to are, do they already this ability, but is the kept silent? Which we're seeing again and again within health technology companies.

Then as they iterate on these products, how do we just make sure this top [inaudible 38:57]? Going specifically into the type of data, we're really interested in the whole breadth of data sources, whether its mobile apps, wearables, sensors, et cetera, that record primary data directly from the patients. Importantly for this to be useful for researchers the data, we feel, must be very well characterized in terms of accuracy and reliability. We're really wanting to understand, is this already being done by companies for other reasons, i.e., for internal uses?

Next slide, please. So, what we really would love to have feedback and what we're considering is we're all for the action plan highlight. We really want to make very specific actionable recommendations at the end of this process to really promote the functionality necessary to support evidence generation and third party usage. So one big area that we're thinking through, what are the market opportunities for mHealth companies to actually do this? Whether it's due to merging market opportunities or the value based payment model change we're seeing in the U.S., or even novel opportunities for partnerships with payers and delivery systems.

So, as we're thinking through, we're also, sort of, really trying to hone down, what are the current challenges in supporting the functionality for evidence generation?

Specifics there include; firstly, is there a lack of interoperability in data standards to do this, secondly, regulatory concerns, thirdly, trade secrets. If a novel sensor companies collecting interesting data, what are the incentives for them to actually share that?

Would love, again, to have feedback on how could we start to address these challenges and what are the highest priority challenges to address, and why? We feel that there surely must be lessons learned from mHealth technology already designed primarily for the research market.

Then, next slide. Again, given my bias towards small companies in particular, we're thinking through the division of the land between large entities and then small, nimble start-ups. Do the incentives and challenges change depending, when we're talking of those two different stakeholder groups?

Going specifically into the large players, we feel that the high profile partnerships may come easier to trusted companies. Since we may already see value in working with researchers, particularly on high profile topics. Again, just the incumbent large size allows them to write to extended development timelines, they can manage risk, they have a lot more cash flow to stick through these issues, as well as being able to leverage legal and lobbying capabilities.

Conversely, small players, where I have a bias that a lot more of the interesting technology lives, they're definitely more nimble and innovative. However, they're uniformly focused on, very often, just one of two things, i.e., getting initial adoption of their business model, so some of the considerations that we're thinking through often don't come top mind for these entities.

So, that's, sort of, the dichotomy of the trade offs that we're trying to dig into, and again, we'd love to have feedback on. However, some of the incentives that we're thinking to, we don't think really make a difference depending on size. Fundamentally the market is really interested in disruptions, in my opinion, in our opinion, that can prove reductions in healthcare cost and can improve quality care as well. As long as there's a linkage and this reliability to clinical data, to generate that proof, we feel that there will be models and a census that emerge.

Fundamentally, we've seen this historically, again, partnerships with large, life-science companies from other entities throughout the spectrum does create fruitful aid business models, but also value to what we're trying to define. Next slide, I'll hand it back to the team.

Christina Silco: Next ... Okay, thank you so much Mo, we really appreciate your comments. Next we have up Seth Clancy. Seth, are you on the line?

Seth Clancy: Yes.

Christina Silco: Thank you.

Seth Clancy: Thanks, and I just want to echo the comments of Ravi and Mo, and thank Duke Margolis and the FDA for sponsoring this important work. It's a pleasure to be with you this afternoon and represent these sponsor researcher perspectives. So, before I begin, I just want to qualify and acknowledge that when we're talking sponsorship here, it's really referring to any organization that's engaged in funding evidence generation with mHealth technology. Those will obviously include entities like medical device and drug manufacturers, but a whole host of other stakeholders as well, that will include clinical societies, patient organizations, hospitals, employers and the like.

There's, clearly, a growing role for mHealth in evaluating particular medical products, and as we think about those potential use cases the first that comes to mind is regulatory decision making, but it certainly doesn't stop there. There are many other use cases that would include quality measurement, value based payment models, communication directly with payer organizations and defining value. Novel outcome measures and then evidence generation that can be employed for patient centric decision making and shared medical decision making. All of which are really important.

In my own experience, we think about our mHealth needs. Often these come up to compliment other traditional assessments, so I'm in the cardiovascular space, it's very common in our clinical trials to include six minute walk test and NYHA. Those are nice measures of functional capacity and well understood. We think about including things like activity tracking as a way to get at functional performance, or how active and functional a patient is in their normal environment, not just at a point in time, but on a more continuous basis.

You could also imagine examples where electronic patient reported outcomes are included, or e-pro. If you're evaluating an intervention, for an example, and you want to understand what the quality of life is continuously, not just at baseline and 30 days post procedure, e-pro and mHealth technologies really allow you to quantify that in a pretty meaningful way. We've dealt with a lot of patients that come to us and ask, "After my intervention, what sort of pain am I going to experience, one day, two day post procedure? How does that compare to day seven, post procedure? Or day two, post procedure?"

While a lot of the conventional quality of life instruments include pain domains and recall windows that go back as far as two weeks, it's really helpful to be able to incorporate in mHealth technology, which allows you to evaluate these kinds of domains on a more continuous basis. Really, flesh out the knowledge and information that you can share and help quantify that for patients so that it's not just anecdotal based on the heart teams experience.

I'll go to the next slide. So, in terms of what the action plan should highlight and look like, you've got to start with understanding where the existing mHealth technology is today. What the strengths, weaknesses and capabilities are of the existing apparatus that's been used. Then, fortunately, there are quite a few opportunities now for improved collection and sharing on the convenience and

accessibility front. The smartphone ownership is just growing and it's pretty ubiquitous among a number of diverse groups and that's really encouraging, certainly if you think about the number of consumers that are wearing activity trackers currently, whether it's Garmin or FitBit. They're already collecting information that can glean additional insights into their own health, or disease progression.

So, from a convenience standpoint, as technology becomes more and more ubiquitous this bodes well for being able to leverage and incorporate off of the shelf solutions to help us in this regard. As well as focusing on more of those medical grade type technologies. All of this enables better virtual data collection, which can have the effect of reducing the time, treatment burden and travel costs associated with patients participating in clinical trials and generating evidence.

There are certainly lessons learned from other mHealth arenas and applications, if you think about clinical decision support and all the work that's gone into building that out in the electronic medical record environment, the clinical trial implementation space. There are lots of places that we can look and learn from as we attempt to get even better at the mHealth application for medical product evaluation and beyond.

Then, finally, there is important points that we'll need to address and discuss with regard to data quality, specificity, validation and methods. In many instances we've got to be willing to make trade offs between high specificity and a highly validated instrument and convenience and ease of use on the part of patients. So, there are going to be circumstances where we have to decide, what will be the best approach depending on our research question and outcome goals?

Sometimes if you have an instrument or a technology with a one year battery life, that is very easy to use and passive for patients to engage with, that is a huge strength relative to other instruments that may be even more validated, but incur additional burden on patients. They have to charge the device daily, they have to sync the device manually and in a regular fashion. It's not as easy access to patient cloud applications that can store that data seamlessly and easily, so it incorporates into the patient's day to day routine.

All of these considerations need to be discussed and agreed upon with regard to this general area of getting at higher data quality, specification and validity, while also preserving some semblance of ease of use, minimizing the burden on patients to the extent possible and really focusing on convenience.

I'll go to the next slide. We talked about this earlier in the day, this idea of fit-for-purpose. So, again, there could be a future state, let's say we fast forward to Christie in 2024, when mHealth technologies are used for primary outcome measure assessment and regulatory approval. That's probably a distant part of our future at the current time point, but that does not mean that mHealth technology isn't useful and can't be used for other things.

So, if you animate two down, please. I'll just note that beyond primary outcome measures, mHealth can be highly useful for secondary outcome assessment for ancillary or exploratory analysis. Where we're really looking at hypothesis generating or validating against other things that we know about a patient's disease state.

Certainly while in the future world we would want to think about mHealth or regulatory purposes, there are lots of applications that can be included, even today, with regard to post market studies, post market surveillance, quality assurance, quality control and real world comparative effectiveness research. You could also think about utilizing this kind of technology to enhance exclusion/inclusion criteria for recruitment and large scale pivotal trials, and doing sub-group analysis or risk adjustment.

I'll go to the next slide. So that brings us to the concept of validation and certainly it's one of the biggest issues around using mHealth data for evidence generation. We really need to understand what people mean when they say validation and we'll have to ask questions about what information needs to be provided. How does that change based on the data type? What information is needed for a pain rating app versus a seizure tracker, for example? Where and when is accuracy essential versus when we can get away with some dirtier, or clumsier, data because it's still useful?

Then, finally, when information should reasonably be provided by mHealth companies and will need to be done by the researchers themselves to push us towards a place where we all feel confident in being able to validate what we're researching and what we're communicating to the broader community.

Advance one more please. So, this is my final slide and it's just a nice example of some validation work that's already been done in the MS space, with incorporating both mHealth data from accelerometers and additional clinical and health information where the attempt is to try to provide some clinically meaningful base line change. That helps us to wrap our head around the mHealth data and makes sense of its utilities.

A lot of these efforts are going on in this space and this will continue to be an area of focus for us in the MS space and beyond. Certainly in the cardiovascular arena, we attempt to do activity tracking, cross-walked against NYHA class, and six minute walk tests. One of our big collective tasks as a community will be helping to define some minimum clinically important difference and then validate those differences so that we can not just generate the evidence, but begin to make real good sense of it and inform that patient decision making process.

So, with that, I've concluded the stakeholder and researcher perspective. Now I believe I'm going to turn it back over to Greg.

Gregory Daniel: Great, thanks to all of you. Ravi, Mo and Seth for walking us through some of the Working Groups thoughts on these issues. We're now going to open up the lines for

approximately the next 20 minutes or so to get participants thoughts on all of this. So, all of you dialed in and listening to this, this is your chance to let us know your thoughts about what we've been talking about so far. So, we put out, sort of, three major groups and ways to encourage engagement and structuring their activities in these areas. User engagement, sponsors/researcher needs, as well as the mHealth company incentives themselves. Stay involved and incentivized to develop these kinds of technologies.

So we'd like to hear your thoughts. Are we missing anything? Is this group going in the right direction? Again, you can use either the raise hands feature next to your name on the webinar, so that we can unmute you, or you can write your comments in the chat box that you should be able to access through the button on the upper right of your screen. So let me turn to ...

Speaker 10:   We don't have any comments just yet.

Gregory Daniel: No comments just yet.

Christina Silco: Okay.

Gregory Daniel: So what I might do is maybe turn it back to our speakers, are there, as you've heard the other speakers. Any thoughts or comments on what your colleagues presented, or any other points that you wanted to make sure got raised?

Speaker 10:   Okay, hold on one second. Let me just ...

Christina Silco: We're working with technology here, so it'll be just a second.

Speaker 10:   Alright, I've unmuted you Joe.

Gregory Daniel: Okay, Joe Dravsta, do you have a comment or question?

Joe: Well, I do have a comment. I really appreciated this discussion, and I'm glad to see that this Work Group is active in this area. It's an area that ... The whole area about obtaining patient information in this systematic way to use in clinical care of individual patients and also in research for its purposes, has been one that we've recognized for a lot of years and just been frustrated not being to get around to. So, I'm very pleased to see this work going on and in such a thoughtful way too. I thought this was ... The presentations were great.

                 Just to, kind of, present conceptually what we've been thinking of. When I say "we", I'm referring to a group here at Mercy in Saint Louis. Well, we've been doing some work incorporating UDI into electronic health information. Creating data that we can use for surveillance and research, but also creating a means to get information on devices into the patients clinical record for use by the clinical team.

                 That's where this, you know, the mHealth comes in and patient reporting comes in. We would really love to be able to incorporate patient data right into all of this,

right into the patient record for use by the clinicians caring for the patients right into our data for surveillance, et cetera. Our view is that we need to make it useful for multiple purposes in order to make it happen in a sustainable way, so that it has significant utility to the clinical team caring for patients, as well as for the patients themselves, as you rightly pointed out.

In order to make it useful for the clinical team, we have to find a way to systematically get the data into the clinical record for review by clinicians as they see patients. Get it into the clinical record in a format that makes it easy to review. If I'm going to have to stop and look at somebody's iPhone in the middle of a busy clinic and look at, you know, blood pressures of the last three months, I'm probably going to slow down and not do that. I'm wondering if that isn't want you found when you were asking clinicians about the use of data from mHealth.

If I click on a screen and all of a sudden there are all the blood pressures in graphic form, and I see them and review them all in one point two seconds, and have additional information. It helps me manage that patients blood pressure. Now you've added value. I don't know that we can get that all done, just talking to the mHealth vendors. I think this is something that needs to be done at the electronic health record level.

So, I'm getting there's two sides to this and I just wondered what people's thoughts were.

Heather Colvin: That's great Joe, this is Heather at Duke Margolis. That is definitely the interpretability and usability of the information is been a critical question and issue. So thank you so much, but I think you do bring up a great point that it needs to be something done in partnership with the mHealth developers and the clinicians who might be using that.

So, I think we have a few more comments. Greg?

Gregory Daniel: Yeah. So, we have a question coming in from Kathleen Basmahjong. She writes, "How do you ensure data integrity, in particular ensuring that the actual data themselves being collected, are actually collected from the patient of interest?" So, that is a really good question, so maybe any of the ... Maybe Seth or ... You might have some thoughts on that piece.

Seth Clancy: Sure, so, it's certainly a big challenge, and I'm not sure we've really tackled that yet, but there is a number of safeguards that can be put in place. That, again, leverage the technology that's available that help give some assurance that you're collecting data in a timely fashion, and the type of data that you expect. Which is directly from the patient when they were supposed to complete it.

So, number one, you can set up your devices in such a way where they have pins, or passwords, that are required to enter, which is one way to prevent other people from entering information. You also have the ability to track, in real time, when the patient is completing the assessments and put together dashboards, so you know

that they've done it within the specified window. That's helpful, again, in validating. When you compare it to an alternative environment, let's say you give a paper-based diary to the patient.

I think you're encountering the same sort of challenges with having to rely on faith that the patient is going to complete it in the time frame that they specified and that it's them in fact doing it. So with technology, we actually may have some additional advantages to ensure with biometrics and through other means, like pin and passwords, that it's the patient, in fact, that's able to complete that.

Gregory Daniel: Great. Thanks for that. Another question coming in from Stuart Grant. His question is, "Does general clinical patient conditions reduce the stickiness of devices compared to specific conditions, such as ALS? What is the current best route to get into the medical record?" So that might go to Ravi, any thoughts on how general, versus specific medical conditions, effect user engagement?

R Ramachandran: Right, thank you. This is Ravi. A couple of thoughts, one of the ... I think, we've, sort of, talked very briefly about this earlier, one of the things we have to address before we go to, how do we get all the data incorporated, is how do we address the question of silence? Even within the EHR system, there are so many different ... You know, one EHR does not talk to the other. If I am in the other [inaudible 01:02:21] and I'm visiting my neurologist, and I'm also visiting my general practitioner. I'm visiting my physical therapist and they happen to be on three different systems, none of the data is going to be seen by the other two care givers unless I actually, physically print out paper records and take it from one appointment to the other.

So there is an interoperability question that we have to address as a group and figure out, how do we incentivize the entire ecosystem going forward, that the data is easily, not only assimilated, but transferable and available to the patient and the care givers in an easily interpretable fashion.

The second thing that we have to think about as we collect some of this mHealth data, is in subject case of ALS for example, to what purpose are we collecting the right data around, for example, respiration? Are we collecting the right data, for example, around growth motor skills, as we collect data for activities of daily living? Will this data toward us, aid a new insight into the progression of disease or therapeutic benefit? Or will this supplement the already existing clinical end points of the physician that are using it in the shared decision making that we all want to get to?

Those are some of the things that we have to think about before we can say, "Here's the data set and the device, or the apps, that actually give us the mHealth data." So, as we think through this, one of the things that I keep thinking about in my day to day job at patientslikeme, is what is the right problem? Are we solving for the right problem? Once we get to what these problems are, then the solution becomes an easier set to deal with.

Christina Silco: Great, and I think that Greg Pappas also joined the call. I think Greg, you had a

comment as well on Ravi's point.

Greg Pappas: Yes. Can you hear me?

Christina Silco: Yes.

Greg Pappas: Thanks Ravi. I wanted to add a perhaps more generic way that linkage between data sets is critical. Alone, there's not much most of these data sets, as standalone, can do. Claims data for devices don't tell us much. EHR's don't tell us much by themselves. Registries, by themselves, don't tell us much. By themselves mHealth data, when we link them we begin to see great utility in that. In fact, the scenarios, the best case scenarios are prototypes from NEST, are those linkage. Indeed, mHealth data coming in for patients, through apps, have been used linked to registries in the orthopedic space, providing really critical information that makes the data much richer and much more meaningful.

So, you're absolutely right, the linkage is what's ... Linkage is a really critical issue.

Gregory Daniel: Yeah, great. Thanks Greg. So, another question is coming in from Pat Baird. Let me just go ... I'll just go ahead and read it. "I noticed one of the slides there is a mention of patient center design and usability literature there's concept of user centered design, or UCD." Pat is wondering if this is the same concept, or if PCD goes beyond textbook UCD techniques? Who would ... Maybe ... Does any of our speakers want to address that question?

Christina Silco: Maybe Ravi? Do you have an idea on that?

R Ramachandran: Alright, so, Pat actually thank you for that question. That's something that I think about often. So, user centered design is a design concept that primarily has three [inaudible 01:06:45].

Gregory Daniel: Yes.

R Ramachandran: To focus on the users and tasks that are earlier and throughout the design process. Measure empirically the user ability during the process and design and test user ability ... Figuratively, that is. You know, test quickly and fail quickly and move on and integrate through the process. So, that's UCD in a nutshell. Those are the three main areas of UCD.

Patient Centered Design takes the same concepts with UCD, but focus more on the healthcare aspect of things. So, while you're doing user centered design in a healthcare framework, what you're doing is applying the same principles, but with the end user in mind. How do we enable the person, not necessarily a patient. You know, because we are talking about health, wellness and disease, so how do we enable the end user of health and wellness to achieve their health and wellness goals in an efficient manner so that they can actually derive the right insights and feel engaged and become part of the process?

I hope that answers the question.

Gregory Daniel: Great. Great, Ravi. Thanks for that. So, I don't see that we have any other comments on this more general discussion of the three different, major stakeholder groups and how to increase engagement. So, we are going to move on to the next portion of the webinar, but what I'd first ask is if during this conversation, if you did have comments on the stakeholder groups and approaches for increasing engagement and incentivizing activity in this area, please send those comments to MargolismHealth@Duke.edu by July 12th. That would greatly appreciated.

At this stage I'm going to move things over to the second half of this presentation. We're going to be talking more about the mHealth data types. I'm going to categorize them into person reported data, task based data and passive sensing. With that, I'll turn things over to Heather Colvin to provide some background on that. We'll also hear from others as well, and then we'll have another section of public feedback and engagement.

So, if you have comments or questions on this next section, please go ahead and start using the "raise your hand" or the chat box to start sending us those comments so that we can get to them in the next sections public feedback. Heather?

Heather Colvin: Hi everybody. So, one of the things that we started to realize was a major challenge for us moving forward was, jargon. As in every situation, every group has their own words and terms that they like to use for things and so we felt like if we all started from a common set of what we mean when we're using certain terms, it would just expedite the process going forward, because we're talking cross-disciplinary.

So, one of the things that we did was we tried to boil down to three main types of data we see being generated by mHealth technologies. One of things we tried to do was to stay away from some of the more specific, kind of, clinical terms and incorporate them into these broader buckets that might have more meaning for mHealth companies and for clinicians and for sponsors going forward.

We broke this up into user reported data, what people tell us about ourselves, themselves. Task based measures, and this is measures of what people would do with a set, set of instructions or activities. Then there's passive sensing. Those sensors where you just wear them throughout the day and they passively collect information about you.

So, when thinking about user reported data we wanted this to be clear, that this is actually the user. We steered away from the idea of patient reported data because, at the end of the day, most people don't think of themselves as patients. Most people think of themselves as people. "Patients are people who are in hospitals", is a comment someone made to us. We also recognize that people move in and out of states of health. You're healthy one day, the next day you may not be, but then you go through treatment and you're improved. We want to capture information

about people as they move in and out of these states of health.

So we specifically shied away from the term patient and instead thinking about this, and people who are adapting technology as users of that technology. It's a simple change, but it's something we wanted to be clear about why we chose that term. This is data that's reported by people, or by care givers of that person, if they are unable to report that data. It can include a hole swath of information; it can be questionnaires, surveys, symptom tracking, it could be a person reported outcomes or patient reported outcomes, which are typically incorporated in some clinical research.

It can also include patient diaries. People are required ... My mom has to report on what she eats on a daily basis as part of her diabetes treatment. People collect this information for a variety of reasons. When I was doing triathlon training I collected information about my exercise regime. So people in different states of health collect information for different reasons.

We wanted to be sure to be clear that this data was not limited to validated outcome measures. Patient reported outcomes, measures, or a prompt are very specifically designed mechanisms to collect information and measure them. We didn't want to exclude those, we wanted to be inclusive of other sets of information as well. Often, just as a point of context, many of these patient reported outcome measures that have been out there for a while and are validated, have been historically captured through other approaches; paper tests, or in the clinicians' office, phone surveys, et cetera.

We also wanted to think about the data that could be collected through different types of mHealth applications. Can we convert what is historically been done in the clinicians' office and on a piece of paper, to something that could be collected through an app?

We started thinking about task based measures, what is it that people do if they're given a certain set of instructions? These are typically objective measures of a persons mental and/or physical ability to perform a test. This is thinking about some of the traditional clinical measures that we see physical functioning, like the six minute walk test that Ravi and Seth talked about earlier. This also could include cognitive functioning. The tests that are out there right now, but also physiological tests performed by the users. So this could be data that's actually actively generated by a glucose monitor and that could be incorporated as one of these as well.

In the past many of these measures were collected in a clinical setting, with a clinical observer, but we see an opportunity, if appropriately done, to transition these clinically observed measures in some cases to things that individuals could do themselves outside of the clinical environment. There's some obvious opportunities here, if appropriately done, to validate that the same level of quality of those measures is done in the home, could save lots of money in terms of clinical visits, time missed from work and other things that would help patients be more

involved and engaged because it's less of a burden. We also think that there could be collected ... These things could be collected through remote centers and mobile applications, in combination.

Then, passive sensing. We think of passive sensing in a variety of different ways, one of which are, you know, the activity monitor watch that I wear on a fairly regular basis. It could also include some of the new technologies that are coming out, and new sensors that are coming out. Bathroom mats that look at weight for patients with COPD, or congestive heart failure. We also have a variety of other sensors that are coming out. Also, there's a whole field around looking at how a mood can be assessed, for instance, based on the persons use of their mobile phone.

So we wanted to be ... We know we don't want to be stuck with the technology that we have now, we wanted to be future thinking about the technology that's coming down the pike. So, I'm going to switch over because Megan Doerr is going to be able to walk us through some of the examples that she has gone through as well. So Megan, I think I'm handing you over the keys to the presentation.

Megan Doerr: Hi everyone. This is Meg Doerr from Sa -

Christina Silco: Megan? I'm just going to ask you to speak up a little, it's hard to hear you.

Megan Doerr: Okay. Maybe this is a little bit better. So, my name is Meg Doerr. I work for Sage Bionetworks, which is a non-profit, think tank based out of Seattle, Washington. Sage worked with Apple on the original release of their research kit apps in 2015. We built a back-end repository for hosting data collected through these apps, as well as developing the consenting process for consenting people to participate in an entirely remote research study. So, I'm going to be presenting some of the data from our Parkinson's mPower study. This data is actually publicly available. Participants consented for its broad release. To see this data yourself, you're welcome to visit us at the Sage website and work you over toward the data center, you'll find that.

Christina Silco: Hey Meg, I'm so sorry to interrupt you, but it is very hard to hear. I didn't know if you could move the phone closer to you? Thank you.

Megan Doerr: Let's see if this is any better. So, the Parkinson's mHealth study involved thousands of participants when it launched in March of 2015. Both people with Parkinson's disease, a soft reported diagnosis of Parkinson's disease, and people without Parkinson's disease were also invited to participate. We had people consent to participate in this study and then we immediately started gathering data in the three buckets that we've described so far.

If we could move to the next slide. So, we collected passive data, we had structured activities and we also had patient reported mdata in the form of surveys. The surveys we used were the MDS, and UPDRS and the PDQ8 PRO's, which are well known and used in clinic for people with Parkinson's disease. We had some

structured activity and also some passive measures that we gathered. You can see here in this graph, we were looking at motor initiation, gait and balance, hypophonia and memory, all of which are effected in Parkinson's disease.

So, I'm going to be sharing with you some of the data from our gait and balance activities. If we could go to the next slide? So, you can see we introduced, these are the actual screens from the app itself, participants downloaded this app onto their phone and then consented themselves and then started participating. The tapping test that measured motor initiation, a gait and balance activity that measured people's ability to initiate activity and their steadiness on their feet. Hypophonia activity, where participants used the microphone in their smartphones to capture vocalization and initiation of vocalization. Then we also had a memory test, which participants liked a lot because it was like a little game for them.

The gait and balance test was a really interesting one when we start looking at the data. If we go to the next slide. The phone has within it a gyroscope, as well as an accelerometer. So we can measure activity using the x, y and z vectors. The x vector, going across the phone. The y vector going up and down the phone and then the z vector going through the phone, front to back. Then use this data to tell us about participants activity.

So if you want to see what the data actually look like, the next slide presents some of this activity. So here is data from a person who was doing a walking activity. You can see their acceleration and then their work against gravity there. So, you can see them walking a fairly steady pace from second zero, over to second 12. You can see in the x and the y and then the z axes there. I'll give you a second to take a look at this to see, to process this data a little bit, but you can see it's pretty clean data and it really can tell us a lot more, one might argue, then just clinical observation alone could about participants steadiness on their feet, the regularity of their stepping, their comfort in walking.

So, not everybody walks the same way. We don't need a Monty Python sketch to remind us of all the silly ways that people walk, but certainly we saw this as well, with our data. The next few slides present some of this silly walk data. This first one, you can see a participant was walking, but holding the phone in their hand and then they stopped walking at four seconds, there you can see a stop. They put the phone into their pocket, button up top down, and they started walking again. So, you can see a difference there in the way that the phone responds and you can see within this data it's pretty clear what's actually happening with the participant.

Although the data is technically dirty, it's not a mystery to us what's happening because we're collecting this granular data, we can understand what was going on. So, it looks like the participant was holding the phone in their hands, they started the walking activity, then they probably read the direction, "Oh, your phone is supposed to be in your pocket." They stopped, they put their phone in their pocket and they continued the activity and completed it successfully.

The next slide shows a person walking. You can see between seconds two and 15,

and then not walking, and then starting to walk again. We had vocal commands that the phone would give about walking and sometimes those vocal commands were muffled by a person having the volume down on their phone, or being hard of hearing and not hearing the phone very easily from its placement in their pocket. So we saw some of this as well.

Any of you who work with real people in the real world, understand this is pretty much par for the course. This exploratory study, you know, to assess points about the different ways that we can use this data, we were really exploring the different ways in which people were interacting with their phones and how well they would do understanding directions and being able to follow them on their own. We found things like making sure that directions were audible, as participants participated in these activities. Also, reading levels being at, you know, the 5th grade reading level, to help participants really be able to understand what we're asking them to do, have helped.

The next slide shows an interesting pattern. So, we have here a person who's walking in seconds one through about 25, and then they take the phone out, look at their phone and then put it back into their pocket, but they put it back in, in the reverse orientation. Which is why you can see this flip on the y axis, from being oriented downward to being oriented upward.

Then one final graph on the next slide. If you look at the scale here you can see the scale is very small compared to the other ones. It looks like, from what we can tell, the person took their phone, they read the directions for the walking activity, they placed their phone on a nearby table and then they started the walking activity. We can see the phone is actually jiggling on the table slightly as the participant does the walking activity. Then comes back and picks up their phone.

So, these are some of the variable ways in which people, in the real world, have already started at interacting with their phones, doing these activities. With the Parkinson's mPower study we found a lot of really interesting data and we, of course, are happy to share this data. It's publicly available, as I said, and if anybody has questions about it I'd be happy to take them.

With that, I think we're back to our question time?

Christina Silco: That's great, thank you so much Megan.

Gregory Daniel: Yeah, thanks. Great. Thanks to Heather and Megan for all of those great comments. We're going to reopen the lines for the next 15 minutes to get your thoughts and comments on these, sort of, categories of data, of technology types. So, earlier, as I mentioned again, please use the "raise your hand" feature. You can email us the comments, although if you can either use the "raise the hand" feature and we'll call on you and unmute you, or you can go ahead and type your comments into the chat box if you want me to read it.

So, let's turn to ... Do we have any?

Speaker 10:   We don't have any right now.

Gregory Daniel: Okay. Heather, do you have any comments?

Heather Colvin: Yeah, actually. I would love it, Megan, if you could talk about, as part of your exploratory research into the viability of the data, if you could talk about, kind of, the population size that you're looking at and how do you deal with potentially some of this dirtier data when looking at larger groups of people and some of the methods? I think one of the key things that we've been hearing is, "Are there really good methods out there for people to use in looking at this data?"

Megan Doerr: Yeah. So, this is a great question. The focus of our initial exploratory work with research kit apps, really was focused on this. We were wondering what we would gather, if anything, and that might be useful. What we found was that making an app based research study that participants could consent themselves to and doesn't require any in-person steps, really drew a lot of participants. So we had tens of thousands of people join the Parkinson's mPower study within it's first 48 hours. It became the largest Parkinson's study, literally overnight, as more and more people joined.

                     Which is amazing and wonderful. Very, very powerful platform to be able to bring the research directly to people, rather than asking people to find their way into a clinic or other place that might be less convenient to them. So, for that reason, it's very powerful, you can get huge numbers of people.

                     The data, though, as you saw, can be dirty. It takes, I think, some greater data analysis skills. I think, though data science is advancing just as fast as our ability to collect the data is and we're now seeing new graduates in data science with very sophisticated approaches to analyzing and cleaning data, but this is certainly not something you can do using an excel spreadsheet. This is something you really do need data scientists on your team for.

                     Also, given the volume of data, you know, I mean you think about the dirty data that Google or Facebook or Instagram collect about people. If you get enough data, the dirt, sort of, starts to fall away a little bit and you can start to see larger patterns. Although I would caution, one of the most important things that distinguishes work like this from data capture in places like Facebook or Google or Instagram, is the consenting process. I think that this is one of the most critical things that we keep in mind as we think about gathering these data and using them as the FDA is proposing.

                     Is that people, participants, really need to understand what it is that they're handing over and be cognizant in what they're doing and what they're handing over and why, when it comes to data collection. Lest we repeat the errors of our predecessors into sleazy and other research studies. I think, informed consent is really one of the critical pieces to mobile health investigation.

Christina Silco: Thanks. Go ahead.

Gregory Daniel: Great. Thanks for that and so, I want to bring your attention, you know, this Work Group has really been working on a simple way to think about these different technologies and to go back to the, almost the framework that Heather presented where there's, like, three different types of data types that would be measurable by mHealth technologies. One would be user reported, where the patient themselves has to, sort of, go in and report their experiences or manually input data. The other category was task based, which measures the effort, or physiology, of your ability to perform a task. Then the passive sensing type of technologies that, sort of, like running in the background as people do their things.

So, I want to, like, check on the groups thoughts on this. Are these the right kinds of categories? Are there other things that the Work Group should be thinking about?

Heather Colvin: So, one of the things that I wanted to bring up is that when we were thinking about these categorizes, one of the key questions that came up was individuals reporting to us their ability to do something, confirming what they actually could do through a task based measure, like a six minute walk test, and then seeing what they actually do on a regular basis with the passive generation. We think the combination of these three types of data can give you a complete picture, or a more complete picture, of patients well being and physical health.

I just wanted to see if anyone had any thoughts about that. I think Christina, do you have a question?

Speaker 10:   "Do you think it's possible to encourage secure data exchange between healthcare organization for analytical ..." I missed that last word and it's not coming through. Presumably it's "analytical evaluation".

Christina Silco: So put this question to maybe Seth and to Meg. I think Seth is still on the line. Do you think it's possible to make these types of arrangements? Meg, I don't know if you've had experience with this?

Megan Doerr: So, right now the precision medicine initiative, the All of Us Research Program, is moving in this direction. Part of the All of Us Research Program will be sensor based measurements that participants will be able to share with All of Us Research Program, which then would be married with a whole host of data types, including electronic health records and other data about their health, claims data and so forth.

So, again, the devil is in the detail of how to create data that's sufficiently well structured, that it can be married fairly easily into these other data types, but certainly as one of our earlier speakers said, the real power comes when we start marrying diverse data types together to get a complete picture of a person's health. Again, making sure that people understand the level of data integration that's happening, the view that people are getting on their lives, researchers are getting on their lives, is really important and can't be understated in how important

it is to be transparent with those data linkages.

Christina Silco: Thanks. I think we have another question.

Gregory Daniel: Yeah, another question from Pat Baird, "I have a generic question for the panelists. What worries you the most about this field? I think the opportunities are great and I truly appreciate their research, but much of my time has been spent on risk management. So, I'm interested in how to prevent things from going wrong." Any thoughts from the group?

Christina Silco: I'm going to actually ... There's two people I think might be good to answer this, first I'd like to put it back to Meg because I think Meg, one of the first things that you mentioned was the need for updating informed consent, making it usable. Then maybe also ask Ravi to weigh in after Meg's comment.

Speaker 10: And Greg ...

Christina Silco: So, Meg, could you speak a little bit about some of the informed consent issues and how that may address some of the risk issues?

Megan Doerr: Yes. Sure. So, I think that traditionally informed consent, in in-person interaction around informed consent, has often been really about a legal document, certainly in recent years. Not really about ensuring that participants are understanding what it is they're actually being asked to do and what it is they're handing over to the research team. When we think about these mHealth based data measurements that we can gather, we really need participants to understand a little bit more sophisticatedly what can be measured by their phone, what we can gather and how we would be using it.

So, creating a transparent, an easily understood informed consent process, which allows for reflection by the participants, self navigation by the participant, allows for time for questions and reflection, I think is absolutely essential. Also, establishing very clear policies when it comes to what will be tracked, when and why is important from the research side. So, we found in the Parkinson's mPower study that participants were very willing to share their data broadly with researchers around the world because they wanted certain protections in place when it came to anonymizing their data.

We also found that participants were much more willing to do passive measurements of their activity, than to do surveys. For example, we found dozens more, like an order of magnitude, more tasks were done than surveys were answered. So, recognizing the type of data that you're going to be getting from people allows you then to shift the focus of your informed consent interaction via phone, to really say, you know, "We know you're going to be giving us this data, this is the type of data it's going to be and this is what we're going to do with it."

Again, making it understandable, making it a covenant between researchers and participants, I think, is essential.

Gregory Daniel: Okay, great. Thanks. Ravi, do you have some thoughts on that too?

R Ramachandran: Yes. Actually I want to echo what Megan just said. Create that covenant of trust between the participants, the patients, the public, and the research community because that is what is the engine that will drive this forward. We all, as a community, have to be very cognizant of that. The other two things with, I think, Pat's question, were, "What are the things that keep you awake at night?"

The other two things are that I think about, worry about, a lot, is data security. We would all love to collect this high density, longitudinal, passive data from patients, but a part of this trust covenant that we all were talking about now, is how do we ensure that the data we collect from our patients, the people, is properly secured, protected, and their privacy is maintained, and the data integrity is assured?

The second, which coming from genomics, is a hard lesson I learned and I want us to all be thinking about this in mHealth, is not to overcompensate under [inaudible 01:38:14]. There's a huge, huge potential in mHealth and we should carefully think through this entire process as we go along from where we are now in 2017 to 2024, is not just collect data, but how do we transform the data into knowledge and actionable insights? That could enable the patient community and the people who are using mHealth data, to move forward in a meaningful fashion so that we do ultimately create the sustainable ecosystem.

Christina Silco: Great. Thank you so much for that comment. Greg Pappas?

Greg Pappas: Ravi said exactly what I was going to say. Now is when expectations ... NEST has great potential, real world evidence as great potential. It's going to take a long time, we've got a lot of work to do. So, we shouldn't have too much ... Too many expectations up front.

Gregory Daniel: Okay, thanks Greg and thanks to all of you. Again, if after this webinar if you have further comments or suggestions, again, please email MargolismHealth@Duke.edu. We're going to go ahead and turn things over to Heather to talk about next steps and action plan content after this webinar. So, Heather?

Heather Colvin: Great. Thank you all for participating. This has been really helpful for us and what we're really trying to do is create a form for you to engage with us and let us know your thoughts. You know, we have a great Working Group with multi-disciplinary backgrounds, but we know that there's a much broader universe of people who are working in this field. So, please see this as an opportunity to contact us, via the information that Greg just gave, with the Margolis website, but I also want you to know that you could just drop us an email. We're happy to take any feedback and comments and incorporate that into the information that the working group has in its discussions.

So, one of the things that I wanted to just talk through was, what's next? What are we doing? So, the plan is, is that the Working Group is going to take it's ongoing

research onto of the feedback from this webinar and start putting paper to pen. Right now we have an outline, but we want to start building that out in a more meaningful way to develop an action plan. We're specifically calling it an action plan because we want it to be real and tangible with next steps.

So, thinking about that, like I said, we've talked through, kind of, the first group of these topics. Why we think this is important? Is there a role that mHealth could play in providing a unique set of data that would be hard to get in other places? To NEST, to support the evaluation of medical devices. We also want to get your thoughts about the different types of mHealth technologies that you know are coming down the pike, that we may not be aware of, so that we can be thinking about, not just what's available now, but what's coming forward in the future.

Please let us know if you have any thoughts about our three big bucket issues; user engagement, researcher needs, mHealth company incentives. We think that, as Ravi said, this is a three-legged stool and we have to address all three of these sets of issues in order to make the vision of making mHealth a viable data source for medical device evaluation feasible.

One of the things that I do want to touch on, as it came up in several places, I think with Pat Baird's questions around, kind of, the risk issues, is that we are looking at the broader ecosystem that is facing technology right now. We will be touching on some of the work that's going on by other groups, while technically not, kind of, in scope for this project we do think it's important for us to address things that are critical moving forward. That being informed consent. Thinking about the work that's going on more broadly with data linkages and interoperability.

Going to Joe Dravsta's comments about how he, at Mercy, and others are trying to put that data forward so that it can actually inform clinicians and that they can have informed shared decision making with their patients. We also are going to continue our work in thinking about fit-for-purpose. Where does mHealth fit into the broader evidence generation enterprise? How does it work with clinical information, with registries and other sources of data?

We are hoping to do this with the idea that we will come up with some recommendations about next steps. Not just for FDA, not just for mHealth developers or for researchers, but for the broader ecosystem in general. What can we, as a community, do going forward to advance the application of these possible technologies to make it a real viable source. We want to get to the vision of that 2024 world.

So, we will be collecting the information from this public comment period. Please, please, please get it to us before July 12th. We have to pull this all together for the Working Group to consider. So, please send us your comments and feedback. I wanted to let you know that all the webinar slides and the recording of the webinar will be available up on the Duke Margolis website within the next 48 hours. So, if you want to go and refer back to some of the materials or have questions, they will be available on our website.

We plan ... Mark your calendars, save the date, we want to have a public release of the action plan on September 15th and that is scheduled for 2 to 4 p.m. Eastern time. We're going to have in-person attendance, as well as a web cast of that release. We will walk through, kind of, the action plan and the next steps going forward. Any questions that you have, all the details of this will be posted on the Duke Margolis website coming forward and registration should be open soon.

If you are interested in keeping up to date with the activities of not just this program, but of the other work at Duke Margolis, please follow the link to healthpolicy.duke.edu/newsletter. Where we send out updates about our activities. We won't spam you, we promise. We only send them out once a month and we try to keep them as concise and on target as possible so that you know what we're working on in this world.

So, thank you all. We really appreciate your feedback and we really appreciate the hard work of all the Working Group members, and particularly those Working Group members who were willing to participate and be panelists in today's call. Thank you so much and have a great evening. I think we have finished the webinar.

Good bye, we'll talk to you all soon. Look forward to getting your comments.

How did we do?

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