

Health IT Standards Committee

A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT



HIT Standards Committee Precision Medicine Task Force Final Transcript July 29, 2015

Presentation

Operator

All lines are bridged with the public.

Michelle Consolazio, MPH – FACA Lead/Policy Analyst – Office of the National Coordinator for Health Information Technology

Thank you. Good afternoon everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Standards Committee's Precision Medicine Task Force. This is a public call and there will be time for public comment at the end of the call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I'll now take roll. Jon White?

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Present.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Jon. Leslie Kelly Hall?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hey, Leslie. Andy Wiesenthal? Andrey Ostrovsky?

Andrey Ostrovsky, MD – Chief Executive Officer – Care at Hand

I am here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Andrey. Betsy Humphreys? Christina Heide?

Christina Heide, JD – Senior Advisor for Health Information Privacy – Office for Civil Rights

Hi, I'm here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Christina.

Christina Heide, JD – Senior Advisor for Health Information Privacy – Office for Civil Rights

Hi.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

David McCallie?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, David.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Hello.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Eric Rose?

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Eric. Jim Breeling?

James Breeling, MD – Director, BioInformatics, Office of Research & Development – Veterans Health Administration

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Jim. Josh Denny?

Joshua Denny, MD, MS.FACMI – Associate Professor, Departments of Biomedical Informatics and Medicine – Vanderbilt; Office of the National Coordinator for Health Information Technology

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Josh. Lisa Gallagher? Mary Barton?

Mary Barton, MD, MPP – Vice President, Performance Measurement – National Committee for Quality Assurance

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Mary.

Mary Barton, MD, MPP – Vice President, Performance Measurement – National Committee for Quality Assurance

Hello.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Mitra Rocca? And I think we have a new OCR representative on the phone, is she on the line?

Christina Heide, JD – Senior Advisor for Health Information Privacy – Office for Civil Rights

Actually that's me, Christina Heide; I'll be the new representative from...going forward. Linda will not be participating.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thank you, Christina.

Christina Heide, JD – Senior Advisor for Health Information Privacy – Office for Civil Rights

Sure.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

And then from ONC do we have Maya or Debbie Bucci? Okay, with that I'll turn it back to you, Jon.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

All right, well thank you everybody for joining us here at the end of July. Very excited about the presentations that we're going to hear today; thank you so much in advance to our presenters for your time and willingness to participate and engage. Look forward to the discussion. Thank you, as always, to our task force members who are giving their time and effort and brain power to...this. In addition to the specific presentations that we have today, we have a number of other ones that we're lining up for future sessions and we'll talk about those in a little bit. Also, we're going to give you a recap of the NIH Workshop that just transpired out here in Santa Clara discussing mHealth and its involvement and the role that it might play in the Precision Medicine Initiative. So with that, I will yield the floor to my esteemed co-chair.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thanks, Jon. I too am very excited about the speakers we have today because I think this is really the glimpse of our work ahead and the intersection of not for profit, for consumerism, for government and the lenses that each of these represent are all of the views that we need to take into account. So I'm hopeful as the speakers talk today, we'll hear from you not just within your lens, but also how you

believe the data recommendations you're putting forward serve the patient themselves and consumer organizations or products that might serve them as well as your counterparts in research and in care. Because it's that nexus point that we really need to design our recommendations for; so please be specific in how you think this world will unfold to serve all the stakeholders. And with that I thank you and look forward to the discussion.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

So Michelle, it's Jon; should we go ahead and charge on in through our agenda and head on to our first presentation?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Sure. I think we're hoping that you'd give an update from your meetings out there.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Oh, you want me to start off with that, I'm sorry.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Yes.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

The agenda I had had our 23andMe colleagues presenting first. Okay, I'm more than happy to do that. So...

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Well, if I'm wrong...Mazen, am I wrong?

Mazen Yacoub, MBA – Healthcare Management Consultant

Sorry, I was on mute. No, I think while we had a little bit of time on the agenda if there was anything we wanted to address with respect to the work plan or the questions that we're looking at, considering for posing to presenters and then I think it went 23andMe and then Jon.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Okay, my apologies. Sorry, Jon.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

No, no worries. It's up to you; Michelle, how would you like us to proceed.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Let's have 23andMe go.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Excellent. All right, colleagues from 23andMe, the floor is yours; I will let you all introduce yourselves since you will do a far better job than I would.

Joyce Tung, PhD – Director of Research – 23andMe

Sure; thank you. So you've got a couple of people here from 23andMe; I'll go first since I'm already talking. So I'm Joyce Tung, Director of Research at 23andMe. I've been here for almost 8 years and I run the research team.

Mike Polcari, MS – Chief Architect – 23andMe

Hi, my name is Mike Polcari; I've been here for around 7-1/2 years and I'm focused on technology across our platform.

Kate Black, JD – Privacy Officer and Corporate Counsel – 23andMe

I'm Kate Black; most of you probably know me; I recently transitioned at 23andMe to their Privacy Officer and Corporate Counsel.

Joyce Tung, PhD – Director of Research – 23andMe

Great. So we'd like to thank you for inviting us to speak with you guys today. So we were asked to speak about consumer engagement in research so we're going to be talking a little bit about our research platform. Next slide, please.

So, I thought maybe it would be helpful to give you a little bit of background on who 23andMe is for those of you who are not familiar with the company. So, we are a directed consumer genetic testing company that was founded in 2006 by Linda Avey and Anne Wojcicki. Anne Wojcicki continues on as our CEO. So currently customers can receive un-interpreted, raw genotype data and genetic results on their ancestry.

W

Sorry, there's...

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Yeah, there's some sort of background noise. If folks on the phone could potentially mute their phones, that would be lovely. Thank you.

Joyce Tung, PhD – Director of Research – 23andMe

Okay great; thanks. So they receive genetic results on their ancestry which, for example, may tell them what continent their ancestors came from and can connect them to genetic relatives. We were recently granted authorization by FDA to market a direct to consumer genetic test specifically Bloom Syndrome, which we hope leads the platform for future work. And at this point we have over 1 million genotype customers. Next slide, please.

So our mission is to help people access, understand and benefit from the human genome and this focus on benefit is where the research primarily comes in. Next slide, please. So how can people benefit from research into human genetics? Well there are a couple of main ways that we think about this. For one

we want to help find the right treatments for the right people; so not only use genetics to personalize treatment, but also understand an individual's risk so we can maximize the prevention of disease. So, for example, we know that it costs about \$15-25,000 a year to treat a person with anti-TNF alpha inhibitors; these are drugs that are often used for autoimmune disease. But we also know that those drugs don't work in 30-40% of people. So can we actually identify the right people to give these drugs to and if they're not going to respond, why spend that money and cause them to suffer the side effects of these drugs when we could be trying to find a better treatment?

In addition we also hope to use this information to help develop better drugs using this genetic and phenotypic data from just everyday people. So we know that it already costs more than a billion dollars to bring a drug to market on average, and a lot of this is due to the fact that most drugs will fail in these very expensive clinical trials. But we're seeing more and more evidence that human genetics, because it provides data from a human model system, actually may lead to finding better drug targets. Next slide, please.

So we'll just now step into giving you a little bit of an overview of our research platform. Next slide, please. So how do people get started? So people, you know, people who are interested in 23andMe come to the 23andMe website and they can order a kit online. And a saliva collection kit is sent to their house and they can, in the privacy of their own home, spend as much time as they like spitting into this tube. And it's from the saliva that we actually collect the DNA sample. So then people will actually take this special sort of anonymizing bar code on the saliva collection kit; they register their sample online and create a 23andMe account, which creates that connection. And then they mail the saliva kit back to our lab, which actually extracts the DNA and then does the genotyping. Next slide, please.

Okay, so one of the first and most important steps in research is actually getting informed consent from the participant to participate in research. So our research protocol and our consent document are approved by an external ethics review board, also known as an IRB. It's very important to us that people make an informed decision to contribute their data to research; I mean, it's not for everybody. If you don't want to do this, you should know what you're getting into so that you can choose not to do it. And what their consenting for is to have their genotype and phenotype data used in a broad range of studies. So for example, the average participant contributes to over 240 different studies; so it's much easier for one person to have a big impact. And so far, just over 80% of our customers consent to participate in our research. Next slide, please.

So there are a couple of advantages on doing research online, I mean, for the individual participation it's pretty easy; they can get involved at any time of day from their couch, in their pajamas and geography is not a barrier. So for many sort of building-based traditional research studies, you know, you actually have to live reasonably close to a study site in order to get involved. And here you can pretty much live anywhere that you have an Internet connection.

In addition, so everybody can be in multiple studies at once; so the average 23andMe participant is genotyped only once, but is, as I mentioned before, part of over 200 studies whereas if you think you would think about, for example, how most genetic association studies are done, they re-genotype an entirely new cohort every time, which is a little bit...could be more wasteful than it needs to be. Next slide, please.

So I'll probably skip over some of the details here, but basically I just wanted to let you know that our genotype data currently comes from what is based on a fully-customized Illumina HumanOmniExpress b-

chip where we select the SNP to provide good genome wide coverage for imputation and we also get coverage of variants that are of known or suspected medical relevance. Next slide, please.

We gather our phenotype data primarily through online surveys that are administered through our website so these are designed by specially trained survey methodologists who know how to collect high quality phenotypic data for research and the topics have a very broad range, anywhere from eye color to caffeine consumption to diseases like Parkinson's disease. And it's set up such that customers can choose to take as many surveys as they want whenever they want; so we don't really prescribe the number or the order.

At this point we've now asked thousands and thousands of questions and we take that data and we organize it into, you know, at this point one or two thousand phenotypes for analysis; so those are the things that set up it's either a case-control study or a quantitative trade study. And we have at this point collected over 250 million data points. Next slide, please.

So unfortunately with the PDF the animation got lost, but here I was just trying to give you a screen shot of what the surveys look like, so, the one that's in the back just shows that there's a list of surveys that people can take and when they choose one, they get dumped into the picture that's actually in the foreground, it's an interactive survey interface where people can choose what answer they want and then we have pretty much almost arbitrarily complex logic in order to do branching. Next slide, please.

So one of the most common questions that you...that we get is, how good is self-reported data? And in fact, I actually was also got the Precision Medicine Initiative Workshop in Santa Clara and again, this question comes up. And so it's something that we've thought about a lot. So there's a couple of things that we do to address this concern. For one, we adhere to best practices and survey methodology; there's a lot of easy ways in which you can write questions wrong that lead to systematic biases, you know, we're aware of these and work to avoid them. We also do a lot of user testing to see if there are places where we can see obvious problems.

Another thing that we've seen is that we can actually replicate genetic associations for hundreds of loci at many, many conditions and so what that tells us is that we're getting the same results as people who did these studies and ascertained the phenotypes clinically. In addition we just have very large sample size and that statistically can help mitigate some of the challenges of misclassification although, you know, always data quality will be an important consideration.

And then another point is that the data are structured for research and collected all in the same way. And I think this actually comes to be pretty important; I mean, another theme that sort of arose at this workshop was the concern about like being able to harmonize data from different sources. And so the more that you can actually use a single platform to collect the data, you just get a lot of efficiencies when you're actually doing the analysis. Next slide, please.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Before you...this is just one interrupting question before you go on and I forget it is, are the questions authored by the research organizations that are participating or are they authored by you?

Joyce Tung, PhD – Director of Research – 23andMe

So there's a combination of a couple of different things. If there is a survey instrument out in the literature that's good and well validated, we tend to use that, if we can. If that topic doesn't...if there

isn't a good instrument for that topic already, then either we'll design it ourselves in collaboration with an external expert or if there is a collaborator that we're working with, then they may help us design it.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Thanks.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

This is Leslie, a follow up question on that. So are you using any sort of common taxonomy that you would see gave you ability to be interoperable with more than just your organization? You've mentioned that it was important that the research data and the data collected all be the same structure; does that also apply for interoperability?

Joyce Tung, PhD – Director of Research – 23andMe

It's a great question. So right now we don't...there aren't any necess...we don't actively try to connect our phenotypes to some, you know, well known taxonomy. For specific projects, for example we've mapped our phenotypes to mesh terms, you know, we're putting in like SNOMED annotations, but it's not something that we have yet had to do in a really systematic way. I don't know if Mike has more to add.

Mike Polcari, MS – Chief Architect – 23andMe

Yeah, I think that becomes really valuable in scenarios where we would be importing medical records or importing drug histories or something like that and today that's not something that we're putting a ton of effort into, but we're starting to get there.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thank you.

M

It may be tomorrow.

Mike Polcari, MS – Chief Architect – 23andMe

Yeah.

Joyce Tung, PhD – Director of Research – 23andMe

Okay, if there are no more questions on this, we'll go to the next slide, please. So we feel that it's really important to keep the customer involved in the research process; I mean, we owe them feedback and results in return for the time and the data that they're donating to us. And our research suggests that it's actually more powerful, it's a more powerful incentive to provide this feedback in context than say like a financial incentive. So again, apologies for the lack of animation because it actually blocks some of the pictures in the back, but I wanted to give you a couple of examples of the types of ways in which we want to make sure that we're sharing these results.

So the one in the back which is from AJHG, so when we do publish our results in scientific journals, we always make sure that we either publish in an open access journal or pay to make the article open access so that a fraction of an oval that you're seeing there is me attempting to circle the part of it that says open access. So, even though the average person may not be super-excited about reading a scientific article, we want to make sure that it's possible and not stuck behind a paywall.

Now another thing that we do, and this is on the bottom left-hand side is that we will blog about the results of our studies and couch the findings in lay language so that people can, that everybody can sort of understand what was found and what their contributions led to. Another thing that we'll do is, if there's popular media coverage of some of the work that we've done, which often again puts us in context, we may send out links to those pieces to our customers by e-mail. So for example the one on the bottom right is a link to an article in the New York Times about the paper that's in AJHG.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Do you target that to individuals based on their actual findings or is this targeted to everybody generically and you just pay attention to what you're interested in?

Joyce Tung, PhD – Director of Research – 23andMe

So things like blogs tend to be, I mean, they're available to everybody. This e-mail was targeted to people who had completed the survey whose data was used in the paper; so that survey data would be used in the paper.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

What about the clinical syndromes like your rosacea there, does that go out to everybody or does that go to only people who have a marker that you think is associated with it?

Joyce Tung, PhD – Director of Research – 23andMe

So we try to target like information like this either to everybody or we will, for example, consider whether people have contributed to the research on that condition.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Um hmm, okay.

Joyce Tung, PhD – Director of Research – 23andMe

Does that make sense?

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

So that would include both cases and controls?

Joyce Tung, PhD – Director of Research – 23andMe

And controls, yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

This is Leslie again; to follow up with that, when you've identified groups, like your Bloom's syndrome you mentioned earlier or maybe this rosacea group, are you doing anything that would help to bind that group together to provide support of each other and is that information somewhat could inform a more broader, interoperable framework for patients?

Joyce Tung, PhD – Director of Research – 23andMe

So, I mean, there's a couple of things that we do, right? So within the website there are forums and people are...customers are welcome to like connect with each other on those forums, and they do either around conditions that they have or sometimes around genetic markers that they share. We also have specific research communities; we have ones in Parkinson's disease and inflammatory bowel disease for

example and so they're actual research studies that are specific to those conditions. I don't know if you had anything else to add, Mike.

Mike Polcari, MS – Chief Architect – 23andMe

And those groups have specific surveys targeted to them and they have specific, you know, periodic newsletters that go out to talk about the research that's going on within that community and how they're...how answering surveys is contributing to that research.

Joyce Tung, PhD – Director of Research – 23andMe

So, are there more questions?

Andrey Ostrovsky, MD – Chief Executive Officer – Care at Hand

I'm sorry to interrupt; this is Andrey Ostrovsky; quick question guys and we can discuss it later in the conversation but while we're talking about communities and populations; have you guys...and I can also just go to the method sections of these papers, have you guys looked at the distribution amongst socioeconomic status levels in terms of participation within 23andMe's research efforts or just on the kind of consumer side in general outside of the research realm? Is there a difference and are there populations that are not participating for various reasons, access or otherwise?

Joyce Tung, PhD – Director of Research – 23andMe

So I don't know if that information is in the methods section of the paper; I think I presented a poster at ASHG like 3 or 4 years ago that might have some of this data. On average our customers are more well-educated and have a higher income than I guess what you might call the average American. They are...customers are about 80% European ancestry and then the rest of it is divided up amongst the other ethnicities. I mean, there is a bit of a range, but I'm just sort of that's the average. Is there, I mean we do see representation from African Americans, Hispanics, Asians, so, beyond that I'm not sure that there's really a huge bias, that's what you're asking?

Andrey Ostrovsky, MD – Chief Executive Officer – Care at Hand

Yeah, that's super helpful and I'm very much getting at SES and education is part of that and I think just for the group to consider putting into context this incredibly interesting company and technology and solution when we think at a broader level about access, equity, those types of issues. I think this is a really important consideration so thank you guys for sharing that.

Mike Polcari, MS – Chief Architect – 23andMe

Yeah, absolutely. So I think the...any sort of socioeconomic bias might be different within our paying customer base than it is among the communities where...

Joyce Tung, PhD – Director of Research – 23andMe

Right.

Mike Polcari, MS – Chief Architect – 23andMe

...the participation is sponsored by a third party. So for example, in our Parkinson's community or our roots community, those were both sponsor communities I believe.

Joyce Tung, PhD – Director of Research – 23andMe

That's right.

Mike Polcari, MS – Chief Architect – 23andMe

And another thing to think about is that part of our FDA clearance included building our reports at an eighth grade reading level and we have...we put quite a bit of effort into ensuring that there's a high user comprehension of all our reports and materials at that level.

Joyce Tung, PhD – Director of Research – 23andMe

I think Mike makes a good point and I would say the other thing is that, you know, we are also moving toward...more and more towards mobile and I think that that may also open up some more accessibility for people, you know, for example who may not have good access to, you know, a computer...a traditional computer anyway.

Andrey Ostrovsky, MD – Chief Executive Officer – Care at Hand

Awesome.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

So this is Jon; this is Jon, all good questions. Quick time-check; we're at 13 of 20 slides and we do have time left over for discussion at the end. We just want to make sure you get a chance to get through all your slides.

Joyce Tung, PhD – Director of Research – 23andMe

Yup, we...I think we'll keep going. So the last point that I wanted to make here is that, I mean in our experience it's making participation research very low friction and like a valuable experience for the participant is really important for incentivizing them to come back, right? So if we can only gather them at one point in time, it's not as great as if we can get them to come back, answer more surveys or participate in sort of longitudinal studies. And what we've shown is, for example, if you can get people to come back to the website just to answer one question, they're likely to stick around and answer a hundred more. So it's really important to keep them engaged in the whole process. And I think that's critical for any kind of scalable research model. Next slide, please.

Mike Polcari, MS – Chief Architect – 23andMe

So I wanted to speak a little bit about our API and how our customers can transmit their data out of the system. There are two main ways that our customers do that; the first is either through downloading their raw data into a text file, which is, you know, you can think of that very similar to how to Blue Button 1, right? And the second is our OAuth 2 base API which creates that sort of trusted, structured, secure channel between 23andMe and a third party. And that third party might be an EMR, a PHR; it might be a toner registry, it might be a researcher creating an application or a research study. So, it could really be any kind of third party. The key aspect there is that we're approving all those third parties for credibility and legitimacy and that they have structured access to particular parts of an individual's account, if the individual chooses to participate.

So what that means is that, for example, if there's a researcher out in the world doing a study on Alzheimer's and they set up their study to pull data into the 23andMe API and I choose to join that study, I can authorize them access to only my APOE result, for example, but maybe not my entire genome. And similarly, I don't even have to authorize access to my name or anything identifying so that it's a good opportunity to create authentication without necessarily exposing any personally identifying information, aside from that one SNP of interest. Next slide, please.

And then I also wanted to talk a little bit about a research portal. And what our research portal allows third party researchers to do is to ask sort of high level questions of our data set without necessarily needing access to individual level information in our data set. So, here's a sort of overview of our database, and you can see we have...we recently announced we have over a million people as members of 23andMe and, you know, 80% of them consent; this is a slightly old slide. And you can see basic demographic breakdowns of the data set. On the left you can see sort of a taxonomy of some of the phenotypes that Joyce alluded to earlier, which we'll get to in a moment. And at the bottom of the screen you can see all of these open access publications that are being generated out of this dataset. Next slide, please.

Another interesting question a researcher might want to know about the people in the 23andMe dataset might be allele frequencies for different SNPs. So you can imagine...so, just as a caveat, all these numbers are for the purposes of a slide; they're not actual numbers. So you can imagine that if there was a very rare SNP and you were designing a drug for a very rare disease, you might want to be able to reach out to people with that SNP. And because the 23andMe membership have consented to, or the ones who have consented to research are re-contactable, this provides an avenue for researchers to engage with those people and ask their...invite them to participate in a research study that's very relevant to them and to their family and any condition that they might have. Next slide, please.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

While you're changing slides, you didn't mention it before, but how many SNPs do you sample?

Mike Polcari, MS – Chief Architect – 23andMe

Oh, great question; yeah, so we assay on the order of a million SNPs...

Joyce Tung, PhD – Director of Research – 23andMe

A little less, about 700,000...

Mike Polcari, MS – Chief Architect – 23andMe

Yeah...

Joyce Tung, PhD – Director of Research – 23andMe

...then we impute to what, like...

Mike Polcari, MS – Chief Architect – 23andMe

Fifteen million.

Joyce Tung, PhD – Director of Research – 23andMe

Yeah.

Mike Polcari, MS – Chief Architect – 23andMe

So, so there's quite a bit in there. So here's an example of a...of one of those phenotypes that Joyce alluded to earlier and you can see the key things that a researcher might want to know about this phenotype are, how many people in the data set have this phenotype? How did you arrive at, you know, classifying somebody as a case or a control? You can see those questions at the bottom that the membership were asked. What's the demographic breakdown and which of these demographic groups might be large enough so that I can run a genetic study on them or invite them to participate in some other kind of study? And, next slide, please.

Joyce Tung, PhD – Director of Research – 23andMe

Oh, okay. So, we just wanted to finish up with just a couple of words about how we use the data. So in addition to our own internal R&D, we do publish a number of papers, so over 30 at this point and you can see our full bibliography at the link that's on that slide. We also have a number of collaborations with academic researchers and it's been a very fruitful set of work. Next slide, please.

We were also asked about a relationship with the NIH so over the last several years we have been awarded four SBIR grants, mostly from NHGRI and I'm not going to bore you by reading out the names of the grants; you can see them there. We also do receive grants from private funders, most notably the Michael J. Fox Foundation. So, I'm not sure if you had any additional questions about our work with the NIH, but, I think that's the last slide with words on it. So, let me open to any questions.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

So, it's Jon again. Thank you all so much. You can tell that like task force members were just raring to go and raring to kind of dive into asking questions, which is fantastic. Mike and I have had a chance to talk briefly prior to this and really appreciate your willingness to kind of help us understand how you're helping people get access to their data and the system...the information systems that you're using to do that.

You know, we have a set of canned questions, and I mean that in the good sense, that we'd like to ask folks and they're teed up in some of the slides. What I would say is in the interest of time that we don't necessarily have to have you try to answer those verbatim in the next 10 minutes, we can try to...back to you if you don't mind and get maybe written responses to those. For folks on the task force, I would love for you all to ask questions now. Remember that the charge of this task force is to try to make recommendations for the Precision Medicine Initiative about data standards and implementation specifications that can be used or should be try...piloted and considered in the implementation of the Precision Medicine Initiative.

So, there were a lot of other good questions that were coming up, but if you could prioritize questions related to the charge. So with that, the floor is open.

M

I have a question, it's...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Jon, this is Leslie and I just had a question. It seems that the phenotype data and genomic data were hand in glove and one without the other seemed incomplete. And so if you could speak to that a little because as we look at data standards to sort of the minimum use case requirement, it seems your example would include a minimum use case for phenotype with patient generated data. Could you speak to that a bit?

Joyce Tung, PhD – Director of Research – 23andMe

So I think the question you're asking is that it seems like genetic data without phenotypic data or the other way around doesn't seem as useful? Is that correct?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Correct.

Joyce Tung, PhD – Director of Research – 23andMe

I mean I would 100% agree, right? I mean, any data contributed is useful, but the real power in what we're doing is connecting the two. I will say that, I mean, I think methods for collecting genetic data are like fairly straight...I mean, they're fairly well figured out now. I think what's really hard, and you'll probably hear a lot of discussion about this is, what is the best way to collect any given piece of phenotypic data?

I mean I think we've heard all sorts of things over the years, you know, devices, EMRs, you know, and self-reported data. I think they all have their pros and cons and together they're quite complimentary for us. I think self-reported data was a good place to start; it can be quite comprehensive because people can go back in their histories. It can be quite flexible and it is something that people can do from anywhere. There's definitely a move towards more passive forms of data collection and I think that's great in terms of completeness; you know, there's probably a little bit more noise in that data still.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thank you.

M

I have a question regarding the retur...the linkage to external sources like EHRs and PHRs. How are people taking these results and putting them into EHRs and what kind of standards are you using, if you are using any?

Mike Polcari, MS – Chief Architect – 23andMe

So we have, I mentioned earlier that the probably best path for that is using our API. We have documentation on our API describing it and typically what you would want to export are genetic data or interpreted data on top of the genetics. The genetic data mostly we use dbSNP to identify genetic mutations. We're moving towards using the coordinate system that's used in BCF, just position and then mutation. And then, you know, for an example you could see Gil Alterovitz at Harvard Medical, they have the SMART platform that pulls in, that connects to 23andMe and pulls in genetic data into their EMR platform.

M

And so, for instance, I know...I'm pretty sure you used to test, for instance, like SIT2C19, loss of function variance and things like that. Would that...those kinds of results would just come through as kind of name value pair data and the importing system would have t...would build an import around that? It's not like the HL7 genomics guideline and things like that yet.

Mike Polcari, MS – Chief Architect – 23andMe

Currently we're not using HL7, right? I think we haven't heard that from customers as a huge demand yet, but I think, you know, as that demand grows, we'll certainly adopt standards. I mean, the key thing that we pay attention to is sort of where's the adoption and what is the demand from sort of the marketplace and so far, we haven't heard that yet.

Kate Black, JD – Privacy Officer and Corporate Counsel – 23andMe

Yeah, this is Kate. I would add from my time working with EHRs, there is not a lot of space in the EHR to intake this kind of information in any type of like meaningful, structured way so as a result, neither the providers or our customers are really looking for that or asking for that yet, but I think if that type of module were to be developed, it would certainly be something that we'd be happy to participate in and look forward to engaging with you guys about.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

This is David McCallie; I've got one question just to amplify on the previous answer. You report out the dbSNP variants, are you also reporting out the interpretations of those like CYP219 status or do you leave that to the receiver to apply the interpretation?

Mike Polcari, MS – Chief Architect – 23andMe

We do report out the interpretation and the interpretation depends upon the jurisdiction that you're in and what the, you know, what product you purchased, for example. So many of our customers over the last year have an ancestry only product and you know, do not receive those interpretations; but the ones that do have interpretations, those are also available through the API.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

And what are you using for a name space for your interpretations? Is there...I'm asking the biomarker question from an EHR vendor perspective. Are you using LOINC or just making them up or is there a different...?

Mike Polcari, MS – Chief Architect – 23andMe

So we have our name space for what those markers are and then as partners have requests for a specific taxonomy that they want us...that they want to work with, I mean, we're certainly happy to work with them on it.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

And do those interpretations ever span multiple SNPs or are they all 1:1 with a particular SNP?

Mike Polcari, MS – Chief Architect – 23andMe

They definitely span multiple SNPs, some of them. Yeah.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

So, it's Jon. Joyce, could you talk a little bit about your experience in sharing data with other researchers; you mentioned collaborations with a number of other researchers and either the things that worked well or challenges that you've experienced in terms of moving data between you all?

Joyce Tung, PhD – Director of Research – 23andMe

So I would say most of the challenges are with respect to sort of our pretty strict privacy guidelines versus sort of the movement within academic research to share more data. Right now I think we...we're, you know, because this is our customers' data and we take their privacy super-seriously, we have fairly conservative guidelines about how much even aggregate data we're willing to share just because statistically you can actually find some things out if you provide enough aggregate data. So I would say the challenges are not so much about like moving the data around from one place to another, because the genotype data is really not that big, once you've actually run the analysis on it. We don't generally

share individual level data. But it's really more about setting guidelines about...around how that data can be used and shared that has been the biggest challenges.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Can the consumer mediate that if they wish to authorize the more open sharing, they can do so or is that not allowed either?

Joyce Tung, PhD – Director of Research – 23andMe

So I mean there's two pretty straightforward ways they can do that, right? So Mike mentioned that they can download their own raw data and they can do with that as they wish. Also through the API, if a researcher requests their data through the API, they can authorize that as well. For certain projects we do have an additional IRB approved consent to share individual level data, and so for those projects people can consent to that additional level of sharing.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Thanks.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

This is Eric Rose, I wonder if I could ask, getting back to standards you use again. Regarding phenotype data like that patient's notation that yes, I've been diagnosed with celiac disease, which by the way, if I caught on the screen shot, it looked like the question was about Crohn's disease, I imagine that was hopefully just a little mistake in assembling the slides.

Joyce Tung, PhD – Director of Research – 23andMe

It's a longstanding typo.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

But are you storing that data associated with any codes from any standard terminologies?

Mike Polcari, MS – Chief Architect – 23andMe

Uhh, so, again that's something that we can do if it comes up. I think Joyce mentioned earlier that in some scenarios...

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Okay.

Mike Polcari, MS – Chief Architect – 23andMe

...we...MeSH codes or something like that to annotate the different phenotypes so we can come up with a basket of autoimmune disorders, for example. But again, it's really on a case-by-case basis and over time, as we're integrating with more and more clinical and third party research institutions, that gets more and more important.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

And as a follow up, would it be helpful to you if there were clear guidelines from a source like the federal government saying, these are the recommended standards to use; don't use MeSH, don't use ICD-9, use SNOMED or use XYZ to...so that you can be sure that the folks you have to send this

information to can handle it and so forth and that you don't have to bother figuring out which ones to use. Would that be helpful or would that be onerous?

Joyce Tung, PhD – Director of Research – 23andMe

I think ultimately we will use whatever the researchers want to use, right?

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Um hmm.

Joyce Tung, PhD – Director of Research – 23andMe

So if they're...you know what I mean, like ultimately when you have research data, they're kind of the customer, right; so I think that would...if they ended up adopting those guidelines, then I think that we would as well.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Got it. And now you mentioned researchers as the secondary users of this data quite a few times, not so much clinicians and do you see sending information to clinicians like, hey, your patient is a 23andMe patient and there's just been a study that's shown that a particular SNP that they have might give them a thousand-fold increased risk for disease X, be advised.

Joyce Tung, PhD – Director of Research – 23andMe

Um hmm.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Is that part of your plan?

Joyce Tung, PhD – Director of Research – 23andMe

Yeah, I mean we do have a pretty solid provider program where we pair with physicians and clinicians around the country and they get involved and get that feedback more directly. I'd say on an average basis, most physicians and clinicians don't have that level of sophistication or interest. We have customers oftentimes who will bring that information to their doctors and their doctors either won't be interested or won't know what to do with it. So, we're at a point that we're not there yet, I think culturally and just as accepted practice in patient care, but it's certainly something that we're looking to drive and our provider program grows every day.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

This is Leslie; I think this is an opportunity to really recognize though that the patient might be the data exchange of one that is contributing this information back to the provider. And I would encourage you and hope that you respond with a written response to the questions we have about data standards for both the phenotype as well as the genotype because I think this is an area of patient-generated data, patient self-identified data that can be very important and help to bring value to the genomic information to the clinical record that might not be there.

The depth of family health history may not be in the clinical record, but once exposed by your work, now begins to provide relevance and context back to the clinical record. So thing that being or, I hope that being passive and waiting for there to be a demand may be short-sighted when you represent such a large group of consumers, so I would...I hope that you will respond to the questions in writing. Thank you.

Joyce Tung, PhD – Director of Research – 23andMe

No I mean...

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

So did...

Joyce Tung, PhD – Director of Research – 23andMe

Go ahead.

Andrey Ostrovsky, MD – Chief Executive Officer – Care at Hand

I'm sorry, go ahead, please just go for it.

Joyce Tung, PhD – Director of Research – 23andMe

So I guess I would say like, you know, one...I think it was Kate mentioned right, like we...we're definitely happy to engage with the clinical community, I think; thus far it's just a relatively small percentage of them that want the data, right? Because as she said, a lot of them just don't know what to do with it, so it's actually a burden to them to receive something that they're not sure how to handle. And I guess the other thing that I would also consider is that there are many aspects of health that are not necessarily clearly captured in a clinical record.

And so I also hope that in this initiative that the work will be a little bit more inclusive and consider things that, you know, not everybody considers themselves a patient. Not everything that is relevant to their health is going to be captured in the clinical record or shared with their physician. So, I mean certainly I think it will be better if we can facilitate better communication between the groups and better data sharing. But I think, you know, it's our belief and I think that of others as well that we'll be more inclusive of what constitutes health.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Precision health, not just precision medicine totally.

Andrey Ostrovsky, MD – Chief Executive Officer – Care at Hand

Yeah. This is Andrey Ostrovsky; I want to dovetail on that point. I think it's a very keen observation around the implications of not...data that currently isn't really captured in standardized form as part of a medical care plan or a medical record. And that information has major implications on various testing and interventions around precision medicine or health.

One thing to just bring to the attention of the group, there is a current body of work within the S&I Framework focused on developing a care plan that is in the long-term supports and services realm, which is kind of the functional counterpart to the medical world of healthcare. And I think that will capture domains that have...that do have implications for precision health including not just what meds are you taking, what allergies do you have? But also things like, what are personal preferences? What are supports and services folks are getting? So that body of work is already happening and I want to make sure that's on the radar of this group.

Another comment, and I think this is key, pertaining to the notion of self-reported survey data; I think that requires a certain level of patient activation. People will actually have to want to document that information and when we're talking about folks that aren't activated enough to either know how to get better or are not activated enough to even want to get better, it's not necessarily their fault, it's just there are many circumstances that play into that. I think that's a serious consideration that maybe

23andMe doesn't have to grapple with; it's a for-profit vendor looking to create appropriately value in a marketplace. But when we're talking about federally funded initiatives that is a serious consideration that I think we have to take into account and that has implications for how we design interoperability standards. So I just want to make sure that's on our radar as well.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

An excellent call out for the radar, so thank you, Andrey. So...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Can I add one more Jon, just one more point?

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

...yup.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

You touched on this, sorry, there's a plane going overhead. The...I think that you touched on this but the information that tells what a patient is not likely to have can be as informative in the treatment plan as what the patient is likely to have. And have you given thoughts, you mentioned early in your slides being able to help with prevention, have you given thoughts to how this might help to eliminate unnecessary escalation in care or anxiety of the patient?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

They don't do that kind of thing.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I'm just asking; they're talking about prevention, what is that in their mind?

Joyce Tung, PhD – Director of Research – 23andMe

So I think we can think about this a little bit more hypothetically, right? So, I mean hypothetically, right, if you can use information, genetic, non-genetic, right, to stratify people into different groups of risk, then you can start thinking about like how do I say tailor a prevention program according to that level of risk, right?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay, thanks, that answers...

Joyce Tung, PhD – Director of Research – 23andMe

And so yeah, people do that already, right? Yup.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yeah, I just didn't understand what your slide meant; thank you.

Joyce Tung, PhD – Director of Research – 23andMe

Sorry. Yeah.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Okay, so thank you for all the excellent questions. We could go on for a while here, so I do hope that my colleagues from 23...first off, thank you so much Joyce and Mike and Kate for being on the phone with us and being willing to engage. I do hope that if you can, you'll stick around for the rest of the call, in particular Joyce, we're going to talk about the workshop and since you were there, if you have anything that you want to add, would love for you to do that.

So, in the interest of trying to keep us roughly on time, I'm going to try to keep this to about 7 minutes so I'm going to be very focused and I'm going to give you just a little bit and then I'm going to ask Josh and Jim and Joyce who were also there if they have anything that they wanted to add. So, Monday and Tuesday of this week, the fourth and final in a series of NIH Workshops meant to help the NIH community better understand how to advance precision medicine and the Precision Medicine Initiative was held in Santa Clara. The topic of this workshop was mHealth and its role in Precision Medicine Initiative.

You have, in the documents for this task force meeting, there is a copy of the agenda, which has questions that were asked and all the different participants. I'll simply say that it was a really engaged group, a lot of discussion about how current researchers are incorporating mHealth into their activities; some discussion about where we might go with some of the mHealth things.

The one thing that I'll highlight, because it was something that I paid attention to because I asked the question, Ram Fish from Samsung was on a panel at the...yesterday and after his presentation I said, so to the extent that mobile wearable data are not yet standardized, are you all in the industry willing to come together and work on standardization of data and not compete around that, but instead compete around other things about wearables and basically he said, yup, that's...I'm willing to commit to that. So that's something that in terms of standards, right, and implementation specs, that hope that as we kind of looked across the sweep of precision medicine that we can think about more.

So let me stop there, Josh, let me turn to you...

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

What did Apple say?

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Apple was not presenting, so I did not get a chance to ask them directly. But, a fair point; so Josh, as one of my partners in crime on this, what else would you like to highlight about the workshop?

Joshua Denny, MD, MS.FACMI – Associate Professor, Departments of Biomedical Informatics and Medicine – Vanderbilt; Office of the National Coordinator for Health Information Technology

Sure. I thought it was a very good workshop and I think you've laid out well kind of its evolution. You know, this is one where we sort of talked about what I think would be the newer domain of knowledge that we haven't...don't have as much experience with, which would be the wearables and mobiles and we talked a lot about a much broader definition of mobile technologies, including those that would just be participant-centered such as at the home. And how we could think about the universe of environmental features and home-based features and sort of wearable devices and the evolution of

wearable to sort of beyond just phones and watches to whatever else that could mean and how we could incorporate that.

With particular regards to standards, we talked about and showed some of the fact that many of these wearable devices produce...do have structured representations, but the structured representations don't have a standards base behind them and they differ and they evolve quickly at current time. So, there are issues around some of those things, but also quite a lot of potential as you see that people are starting to use these devices in studies and certainly using mobile technologies for consent and all that kind of thing, which is something that has big impact, obviously, as we think about a million or more people across the country and interacting with them through lots of different studies.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Excellent. Thank you. Jim Breeling, our colleague from the VA, anything that you wanted to add in terms of what was said?

James Breeling, MD – Director, BioInformatics, Office of Research & Development – Veterans Health Administration

Well, I think that it was pretty impressive how the first generation of these wearable devices, you know, being driven by venture capital and being oriented to a consumer market and what is clearly a second generation of devices that's coming that the manufacturers are interested in targeting the healthcare market specifically, not direct to consumers, but direct to cadres of patients. So, that's...I think that they see possibly the healthcare market as being more profitable than sort of the athletically fit individual who wants to train for triathlons or something like that. They really see that.

I think that it really does add a level of complexity because the Million Veteran Program, we already have a sizeable infrastructure stack of IT that handles recruitment, enrollment, electronic data capture in a standard way with surveys and questionnaires and it handles the bio-repository, it handles the genomic data, it handles the EHR data that we have. And if we were to contemplate having to integrate into that IT stack a near real-time patient-generated data streams from wearable devices where you're getting physiologic behavior on environmental feeds in near real-time, it becomes a staggering IT problem, I think, just in terms of the size of the data. I don't know if we spent enough time talking about that at the workshop.

The other thing is that we in the VA do have extensive home tele-health, we have devices in the home, we have at least 20 mobile Apps that are in our App Store, so we're already feeding the patient-generated database that we've got. But it really requires an extensive help and support network for the patients at home. The home tele-health service is delivered with literally hundreds of tele-health coordinators; there's a help desk, there is extensive coordination of the care once you put a device in a home, let alone put it on their Smartphone or their tablet or their wristwatch.

So, it would be a considerable undertaking, I think, if you were to say let's do this for everybody in a cohort of a million people. I think that if you were saying, we've got a cohort of a million people and we have subsets of people we have special interest in, and we don't think that our traditional surveys and our traditional electronic medical record information is sufficient to characterize them, then we could look for targeting them with a continuous data feed from a wearable device or a home hub, something like that. And that's where I see the benefit.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Excellent, thank you, thank you. Thank you, rich comments. You know in the...I knew I was in trouble when like the cloud guys in the room started...their eyes started to bug out about the amount of data that we were talking about, like uh oh, that's bad.

So, you know, the other thing...one other thing I want to add about timeline, okay, so I said this was the fourth of four workshops; they were held starting back at the beginning of the year. There...this was all meant to inform a working group to the Advisory Committee to the Director, which is an...the NIH's Federal Advisory Committee. That working group is starting to work on recommendations, okay, draft recommendations to be discussed amongst themselves and they're looking early this fall to make those recommendations to Dr. Collins, for him to consider in the rather rapid subsequent rollout of NIH funding opportunities.

Which is why, if you look at our timeline for this task force, there's a slight feeling of a forced march to it, but...just I'm doing my best to keep us aligned, in terms of recommendations, at least initial recommendations, that can feed into that timeline as well, so these recommendations can be relevant to NIH funding opportunities for fiscal 2016. So, Joyce, since you were also there in the room as a non-fed, were there other perspectives that you wanted to add?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

I think they dropped.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Oh, okay alas. All right, no worries. So I know...I ran a little bit over what I wanted to, I'm sorry about that. Does anybody wan...on the task force want to ask questions about the workshops?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

This is David; I just want to make one of my tempering comments about the big data stuff is, you know the thing that we have to worry about as much as not being able to handle all that big data is the problem of drawing false conclusions from such a high dimensional space where you will just by random statistical noise have an astonishing number of things that look like positive associations. We need to know what problem we're trying to solve before we go sensorizing everything.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

That is a fantastic observation. You know, the methodologist inside me just screamed out, YES. So thank you for saying that. You know, one thing that I will say is that, you know, Francis, I said this during the workshop, but Francis Collins has this way of like honing in on stuff. I don't know how he does it but basically towards the end he said, so, we really need focused use cases in terms of what we're trying to do with the initiative because otherwise all this is going to be a big bowl of spaghetti. And everyone looks and said, yup, that's right. So discussion of use cases was a clear part of the workshop and will come out and so yes David, your point is exactly right that you've got to be pretty focused in order to get your message right so you can, you know, assign validity to what you're...the conclusions that you're drawing and what you're trying to change. So.

Joshua Denny, MD, MS, FACMI – Associate Professor, Departments of Biomedical Informatics and Medicine – Vanderbilt; Office of the National Coordinator for Health Information Technology

And David, this is Josh, just to reiterate. We are thinking about that as well as the other problem, like the...those of you who are clinical I'm sure remember the CASS trial where we thought suppressing arrhythmias, you know sort of incidental premature ventricular contractions that we found would surely help people because they're not supposed to have those. But in the end...so, I think we're well aware of the challenges both from a high dimensional investigation component as well as the, you know, what might we observe that we have never had the capability of observing before that's incidental and not actually needing to be fixed.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yeah, that's a great point. I really wanted to ask the 23andMe participants about their attitude towards incidental findings and the clinical power of their observations, but I think they're enjoined against talking about that from the FDA ruling. So, maybe in some settings we can...we could explore that.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Sounds like a beer summit to me. So I do...I want there to be more discussion; however, I also want to make sure that Sharon and her IOM colleagues have a chance to make their presentation. So, if we could hold further discussion until we get towards the end, I'd appreciate it. So with that, let me turn to our...Sharon, are you on the line?

Sharon Terry, MA – President and Chief Executive Officer – Genetic Alliance

I am, yes.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Excellent. Thank you so much for joining us and taking the time. You again are also one of those people that busier than the known universe ought to be able to allow; so we really appreciate your willingness to come to us and talk about what you all are doing, so please take it away.

Sharon Terry, MA – President and Chief Executive Officer – Genetic Alliance

Happy to be with you all and I think most of you know, I served on the HIT Standards Committee since the beginning, this month being my first month not on it, having rotated off; so, delighted to present. I'm going to talk about the roundtable on translating genomic-based research for health; you can see the slide there on your screen and I assume you guys are controlling the slides. I have chaired this committee for about 5 of its 7 years of existence and so it has been heavily influenced by the HIT Standards Committee work; they've been complimentary to one another. Next slide.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

And actually before you go to the next slide, just a reminder to mute your line if you're listening intently but breathing heavily at the same time.

Sharon Terry, MA – President and Chief Executive Officer – Genetic Alliance

Yes, good breathing. So, the roundtable is part of a set of roundtables and fora or forums, depending on how you want to say that that the Institute of Medicine sponsors and sponsors get together and actually create. It was created by Francis Collins, Alan Guttmacher, a whole host of a number of others of us

about 7, almost 8 years ago now. And they essentially are places to do a deep dive into various topics that provide a mechanism for interested parties to get together, realizing that there is conflict, but not letting that conflict kind of rule the day. And at the same time, creating a very close and trusting environment for real clear conversation; so lots of good, really good dialogue across sectors. We try to illuminate issues and potential solutions and we've been trying to be very forward looking.

So you can imagine that when we established ourselves almost 8 years ago, it wasn't clear what the HIT infrastructure would look like, what the clinical interface between genomics and the world would look like, but we were really trying to push that envelope. And essentially we had this improving health bent focus, looking at the translation of genomics and genetics for medicine, public health, education and policy. Next slide.

So, I'm not going to go through this, but you can see here is the membership; it rotates every couple of years and people come in and out of it. As I said, there's industry, academia, advocacy, clinical and so on. We have a very nice broad swath. We also have a number of government representatives so, NHGRI and IMH; others have always been part of it as have HRSA and CDC. Next slide.

So our major focus areas, what I did is I highlighted some of them in red and looks like I also made a few errors in the slide typing, sorry about that, that I think dovetail with the Precision Medicine Initiative. And so certainly the area of molecular diagnostics, evidence generation, coverage, reimbursement policies, co-development and companion diagnostics and those have been covered by some of the workshops that the PMI has run, but we particularly looked at how do we get under the hood a little deeper, not just say oh, we need evidence to use these technologies and systems, but instead, how do we get beyond that to implementation and co-learning while we implement.

In the drug discovery realm we've used that to dive into things like pre-competitive collaborations, data sharing, those sorts of things and then spun-off other activities like the data sharing work that the Institute of Medicine did that I chaired that resulted in some recent recommendations. And then in the genomic medicine area, we looked very deeply at the ELSI issues that are relative to this, the HIT issues as well and again, lots of dovetailing with Standards and Policy Committees. Health economics, I think, has also been another place of intersection and then next-gen sequencing and certainly lots of other areas that may...I think all these things do converge, which is an amazing kind of aspect of the times we're in, but those were the ones that I think made the most sense. And we have reports on a lot of these, so happy to either point you to where to download them for free off the Internet or we can get copies of them sent over to whomever. Next slide.

So our impact really has been collaboration and partnerships. We've had impact on policies and we certainly are a resource, so we want to really recommend that instead of reinventing the wheel, and even some of the questions I heard as I got on the call a little early, there are...those questions we have dug deeply on and have lots of information about, having had many of the same players that are now appearing at the workshops and stuff, appear for us and then really going into closed sessions and other sessions with those people and being able to dig deeply on the questions. Next slide.

So our impact; there's a whole host of them but again, I just highlight a couple; so one that I call out is fostering the representation of genomic information in the EHR through a stakeholder-driven collaborative project that has agreements from the leading EHR vendors to develop modules that integrate into their existing platforms. Some of you are very well aware of this and are participating. This includes something called an Action Collaborative is a new method for the Institute of Medicine to work

in the world. One of the maybe you could say problems with the roundtable and fora is they're not allowed to make recommendations, partly because they are filled with people who could have conflicts and who have agreed that they're sitting there because they have interest.

And so the action collaboratives allow people to get together and actually do something that could result in a tool, it could result in recommendations, it could result in something else. And then some of these have also spun off into consensus committees, which again, I think you're pretty familiar with and those are the actual bodies that do make recommendations.

In terms of policy, we were impactful in getting NIH to examine the economic determinants and consequences of personalized medicine and then also NHGRI development of a database of genetic variants with annotated information and potential clinical impact. And then lots and lots again of reports and other kinds of documentation that is freely available and we're happy to share. Next slide.

So the Genomics Roundtable in 2014, the year that just passed, we had 6 working groups and two action collaboratives. You can see here again a number of these and happy to have you just look at these slides and see if there's more information you want from us at some point. But we have worked in an especially interesting, probably a global genomic medicine collaborative that's led by Geoff Ginsberg, who sends his regrets he's not available today and Robin Ward; and they have looked heavily at issues in the IT and bio-informatics space, as well as some of the other areas that are really critical on a global level. And then a whole host of other groups that have done a large amount of work on various issues and then the EHR Collaborative, that I mentioned previously, with Sandy Aronson and J.D. Nolen looking at use cases and standards. Next slide.

So the areas that we advanced, I think, again, highlighting the ones that were relevant; I think all of them were. And I think all of these things kind of lay some great groundwork for the PMI and for work that this task force might do. So we looked at standardizing DNA sample collection from clinical studies. We looked at improving genetics education for non-genetics professionals; that's going to be a very important piece if this is truly participatory as it's been proclaimed to be.

Use of next-gen sequencing, exploring genomic-enabled drug development, incorporating genetics and genomics into learning health care systems to generate knowledge. Again we're really looking at how do we not wait and build evidence like the early days where we all thought we should come to high bars, but instead, do this iterative learning so we can learn as we go and then the two action collaboratives that I've already mentioned. Next slide.

So our activities were a host of workshops; I won't go over those and then also the EHR Collaborative advances, and so those I'll just mention briefly, because I think they might be the most relevant. We identified the minimum data elements necessary to be represented for both germline and somatic genetic determinants; completed a data mapping process to facilitate the development of clinical decision support based on genetic and genomic information. And then pilot projects established to represent pharmacogenomic use cases; again, some of you are very familiar with this, Cerner, ARUP Laboratories and Intermountain. Next slide.

And I'm not going to go over this; again, it'll be in the deck that I'm sure you'll receive, but essentially looking at how do we represent that information in the electronic health record and again, working with lots of good partners who are on the ground and in the field on these issues so that this is actually useful. Next.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Sharon, I'm a little disappointed you're not going to read them...

Sharon Terry, MA – President and Chief Executive Officer – Genetic Alliance

No, I'm sorry.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

That's okay, you're all right.

Sharon Terry, MA – President and Chief Executive Officer – Genetic Alliance

It could have made everyone's day, I know. And then again, roundtable reports in which we really have, since the beginning, and I think all the roundtable...tried this, but we've been really holding our own feet to the fire about making the recommenda...well again, they're not recommendations, but the findings of each of these roundtable workshops that then result in a report, to make sure that they are very concrete, very real, very real-world and not aspirational, except where we think we need to be driving toward something that we heard consensus about. So, lots and lots of good fodder we're actually in the process now even of trying to do some kind of cross-fertilization essentially of these various reports because at this point, 7 years in, we really have a ton of information.

Just talking to the new director, we just lost Adam Berger to the FDA which is not a bad thing, to their precision personalized medicine group and now have Sarah Beachy and she and I are looking at how can we almost Wiki-ize this stuff so that it can be cross-referenced amongst its own bodies of knowledge. Next slide.

So 2015, another thing that's been a hallmark of our roundtable is that we don't stay static and I'm a particular person who pushes us, being very strategic, very regularly. So we just finished another strategic planning process whereby we've now brought ourselves to this configuration. We essentially still have our two action collaboratives going on, but we're setting up a third action collaborative, the Genomics and Population Health Action Collaborative and also have now boiled it down to three workgroups, Discovery, Evidence for Policy and Practice and Implementation.

So some of the earlier work we did we felt was productive and we could move on from that work not needing to keep the same kinds of things going, and then also have continued to look at a whole variety of issues as we need to, and certainly precision medicine comes along. And again, I'm particularly feeling all these convergences having served on many of these national and international committees; Global Alliance this, International Rare Disease Research Consortium, etcetera; whereby I think we're starting to see that we have before us a lot of opportunity and a lot of the raw materials.

But how we assemble those, something like the PMI, I think, is really a good testing ground for how we're going to put those together. I'd add to that PCORnet, which I'm serving in the coordinating center role with Rich Platt and formerly Rob Califf and now Adrian Hernandez; same thing. We're really trying to...when you apply this stuff in the field what happens and what do we learn and how fast can we share our failures and find new solutions. Next slide.

And then in 2015, here's our plans; implementation science approach to medi...genomic medicine, which we'll be having in November. Catalyzing actionable translation of genetic knowledge into discovery of novel and targeted therapeutics; we have a workgroup set up looking at that, may result in a workshop, we're not sure. We also don't want to just always have a workshop; we're trying to find other ways to engage. Enabling stakeholder decision making in precision medicine by identifying the evidence gaps, prioritizing translational research; again, this is more the implementation work. And then our two action collaboratives; and finally our third one, which I didn't highlight in red, which...will probably shoot me for but looking more on the population health side, which I think the PMI definitely will dovetail with but is not, I don't think, the more immediate need of the PMI as it gets revved up. Next slide.

And there's Sarah Beachy's contact information; she's the Director of our Roundtable, but Geoff Ginsberg and I are both happy to answer any questions at any time. Thank you.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Wow, tour de force; thank you, Sharon. So there's a huge amount, not just in your slides, but also in the Roundtable's proceedings, findings. I think there's a tremendous amount of rich stuff for us to dig into. I'm going to reserve myself for that offline. Given our time, I would love for Leslie or other task force members to ask any questions to ask any questions or bring up any points that you'd like to bring up to Sharon.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Jon, do you envision that Sharon...thank you Sharon, Sharon will be also answering our just routine questions that we'd like to see specific recommendations around?

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

I think that's a good model. Again, we could kind of run through the litany of questions, but I think that forwarding them to Sharon and to Sarah and to Geoff and letting them kind of bring back a response to those, that would be a great way to do it.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Great; thank you.

Sharon Terry, MA – President and Chief Executive Officer – Genetic Alliance

Yeah, that sounds terrific.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Well, since I just committed you to extra work, sorry.

Sharon Terry, MA – President and Chief Executive Officer – Genetic Alliance

Yeah, thanks so much.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

This is David; one observation, Jon, obviously that the action collaborative is...has done work that we should familiarize ourselves with; I looked at it a while ago and my recollection is that it's somewhat

more detailed than the level that we're talking about, but it obviously is...they've done a lot of the work that we should certainly take advantage of. But Sharon, my broader question is, just as someone relatively new to this space, it sure seems like there are an awful lot of global alliances to do such and such and such and such. Are there too many cooks in the kitchen; how do you keep it sorted out? What is the G2MC and how does that compare to the GA4GH?

Sharon Terry, MA – President and Chief Executive Officer – Genetic Alliance

Yeah, that's a great question, David. So we...the Roundtable has always said, we really don't want to create anything that isn't needed or new or just because it's new, we instead want to be in fact a network mapping organization that connects dots and leverages resources. So we've several times created network maps of all of the resources and projects that we've seen out there.

The...and I wish Geoff were on the phone because what Geoff saw is the need for the, and you said it better than I did, I would have to look back at the deck, those letters are...was needed...that action collaborative was needed because it was really looking at things more clinically than the Global Alliance. I'm on the Global Alliances' regulatory and privacy and security board and our work has basically been pretty basic in terms of linking data sets and beginning to look at infrastructure. Whereas what Geoff is driving toward is really clinical application and so the work is pretty different.

And again, we'd be happy to get summaries of both of those action collaboratives that are up and running to you guys, because I think they would be very useful. And the EHR one, it might even be useful for some couple of you to have a conversation with the folks who are working on that one.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yeah, I definitely think so. Thank you.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Other questions from the task force? All right. Sharon, thank you so much and again, we really appreciate both your effort on this over years, but...and also on the Standards Committee over years, but you're really well-focused presentation to us today. Thank you so much for the time.

Sharon Terry, MA – President and Chief Executive Officer – Genetic Alliance

You're very welcome; thank you for your work.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Yeah, you bet. Okay, so we've got 6 minutes left. We have a public comment period here. The one thing I'd like to do before we move on is, can we go back to the slides that show the timeline, because I just want to kind of revisit this with everybody. I know Michelle wanted me to do this at the beginning, sorry Michelle. But, yup perfect; right there.

So we're at...we're on the second line there, we've had our kickoff and we've had initial set of presentations from experts. We've got two more slots, next week and then on August 19 for presentations from experts and we've got some folks lined up for next week and, as an aside, I will be not available next week so you will be in the capable hands of Leslie running the show by herself. But if you have...we've gotten some additional ideas from folks for additional presentations, but if there's more, please feel free to send them on to us.

And then after that, after that Wednesday August 19, we're going to look at starting to put together preliminary recommendations. We're going to go based on what we know is happening in terms of the Precision Medicine Initiative, we're going to go based on testimony that we've had and the expertise of you on the task force, but we're also going to go based on previous Standards Committee recommendations to the Secretary about standards and implementation specs to be used. And then it's pretty fast after that is that we're going to meet on September 10 and try to finalize at least, like I said, initial recommendations and then present those at the September 22 meeting.

So is there any discussion from the task force about this? Are you all okay with this? Does anybody get the heebie-jeebies looking at that?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Jon, this is David; I mean, I think I registered this concern before but I'll register it again. We can't make things happen that haven't happened yet so it may well be, and I think we will discover that there aren't any good standards for many of the things that we're being tasked to recommend. And I just hope that we have the nerve to be able to say that and not to pick a badly implemented standard or an incomplete standard and endorse it, just because we had some expectation. I mean, this is the fault of a lot of standards work; if you develop a standard outside of a clear-cut business driver, you usually get a very bad standard and the integration of this data into the clinical process is not a well understood business driver yet. It's starting...

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Just speaking for myself, I'm counting on that nerve. And it's more to the point that, you know, I don't think, you know, when I participate in a lot of these precision medicine discussions, okay, you know, I think that there is a, what's called a hopeful expectation that standards are going to fix a lot of the problems. And I think that, you know, when properly used, like any good tool, right; standards can help fix a lot of things. But I think that the clarity that this task force and the Standards Committee can bring to that discussion is hey, here are standards that are good, that we've recommended before. Here are places where we think that there are gaps; and that's what I tried to lay out at the beginning. So yeah, I'm counting on that nerve personally to be able to say, you know, to the degree that we can in the time we've got, where there's good stuff but where there's not as well.

Mary Barton, MD, MPP – Vice President, Performance Measurement – National Committee for Quality Assurance

Well this is Mary. Jon, you may have said that before but it helps me very much to hear you say it again, so thank you.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

My pleasure, I love hearing myself repeat myself so...

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Jon, this is Eric Rose. One thing that I do...that I think we should be very careful about is to make sure that we get as much knowledge as we can about the standards that do exist to represent the information's relevance to precision medicine, particularly the genomic and proteomic information. And

we heard a little bit about that from the...today, from the folks at 23andMe, you know, using the...was it RPSNP, which I hadn't heard about before...

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

DbSNP. DbSNP.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

...dbSNP, thank you, yeah, sorry, I misremembered it. And so it looks like we have hopefully enough presentations from experts to orient us to what those terminologies are, what those standards are, where the gaps may be, what they're good for, what they're not so good for and so forth. But I think that in order for us to be done...to be ready on September 10, we've got to make sure that those presentations on August 5 and 19 really cover the gamut of everything that's out there that might be relevant, in terms of candidate standards.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Okay. Well taken advice; we will, at the staff level, get on it; but like I said, any additional recommendations that folks have, we're happy to take them so it's a great point.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

So...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I do think...this is Leslie and I just...I think it's important too that when we talk about the standards that are available, we have opportunities for transport, we have opportunities for just doing basic interoperability from existing standards that can help drive a use case because the data can get from point A to point B. And help develop demand so that we can get to the specificity; maybe we can't justify it today. So I think it's important to sort of the refrigerator versus the bread basket level, what can we recommend today that would help to drive, to David's point, develop need, see that, boy, I want that data, gee that's helpful, that got to me easy. Now my next level of need will be the granularity needed to make this specific to this patient. So, I think we have some standards.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

But I would...I would, the worst thing we could do would be to recommend a bad standard. It would be far better to say this is a promising start, we recommend it be pursued and revisited and iteratively developed, and I think that's where we'll land, frankly, to bias the conversation. But to pick something because it's the closest fit, just because it's the closest fit would be, well, it'll be ignored, for one, I mean, you won't get people to use a bad standard; we've seen that.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yeah, David, I'm just more up on the very big level which is this is data coming, at times maybe it's patient-generated health data that's the basic information we've heard that isn't...that there might be a need for in family health history, followed on by more specifics that are coming...

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

...from the genomics data that we...today we may not have enough information to make a recommendation. So it is iterative starting at a very high level down to further specificity at a later date.

Joshua Denny, MD, MS.FACMI – Associate Professor, Departments of Biomedical Informatics and Medicine – Vanderbilt; Office of the National Coordinator for Health Information Technology

If I may chime in on this, I think to some degree since we're thinking about the...this data is probably or these data are probably going to reside more for research use cases, the standards around genomic data and other -omic data probably are not as important as standards around transport of just EMR, EHR data.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Correct. Correct.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Well I mean, I'll again display my biases, since we have a limited amount of time is, the most important thing we could do is to get a reasonable, complete family health history incorporated into the EHRs. There's more power...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

...there's more power...more predictive power in a complete family health history than there is in a whole x-ome or whole genome study today.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I agree.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

I mean, and there aren't...the HL7 standard to do that in the V 2 space is totally inadequate, the V 3 is a disaster, FHIR is on the right path but isn't there yet. I think we need to encourage that to get finished and then go do some pilots with the 18 existing FHH tools deployed to vendors and then come back in a year or two and see how well it works.

The workflows have to be figured out, the questions of who has the...who should create the data. Who has the right to edit the data? How do you get family members to collaborate if they want to? And how do you track the fact that they don't want to, if they don't want to share with each other, which is frequently the case? Those are all things that are within scope of a couple of years' worth of work and I really think we...if we don't address that use case, we're going to be...we'll regret it.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

All right. So that is some very good, level-setting and norming amongst us, so I appreciate all those comments and I'm aligned with them. We are at the end of our time, we're actually over the end of our time, so, I appreciate your attention. Michelle, if we could turn to the public comment section.

Public Comment

Lonnie Moore – Virtual Meetings Specialist – Altarum Institute

If you are listening via your computer speakers, you may dial 1-877-705-2976 and press *1 to be placed in the comment queue. If you are on the telephone and would like to make a public comment, please press *1 at this time.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

It looks like we have no public comment. So thank you everyone and thank you to our presenters.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

All right, tune in next week for another exciting installment; take care everybody.