



**HIT Standards Committee
Precision Medicine Task Force
Final Transcript
March 30, 2016**

Presentation

Operator

All lines are now bridged.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – 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 today's call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I'll now take roll. Leslie Kelly Hall?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Present.

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

Hi, Leslie. Andy is unable to join us today and Andrey Ostrovsky is not able to join us either. Betsy Humphreys? Marissa Nguyen for Christina Heide?

Marissa Gordon-Nguyen, MPH, JD – Senior Health Information Privacy Specialist – Office for Civil Rights

Yes.

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

Hi, Marissa. David McCallie, I think David made it.

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. Dixie Baker?

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

I'm here.

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

Hi, Dixie. Eric Rose? Gil Alterovitz?

Gil Alterovitz, PhD – Faculty, Center for Biomedical Informatics – Harvard Medical School; SMART/FHIR Genomics Lead

Alterovitz, here.

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

Hi, Gil, thank you.

Gil Alterovitz, PhD – Faculty, Center for Biomedical Informatics – Harvard Medical School; SMART/FHIR Genomics Lead

Hi.

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

Jim Breeling? Jon White? Joyce Sensmeier?

Joyce Sensmeier, MS, RN-BC, CPHIMS, FHIMSS, FAAN – Vice President, Informatics – Health Information Management Systems Society

I'm here.

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

Hi, Joyce. Ketan?

Ketan Paranjape, MS, MBA – General Manager, Life Sciences and Analytics – Intel Corporation

Yes, Ketan Paranjape is here, good morning.

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

Good afternoon.

Ketan Paranjape, MS, MBA – General Manager, Life Sciences and Analytics – Intel Corporation

Oh, sorry.

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

Matthew Might?

Matthew Might, PhD – Visiting Associate Professor - Harvard Medical School; President – NGLY1 Foundation

I'm here.

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

Hi, Matthew.

Matthew Might, PhD – Visiting Associate Professor - Harvard Medical School; President – NGLY1 Foundation

Hi.

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

Mitra Rocca?

Mitra Rocca, PhD – Associate Director, Medical Informatics – Food & Drug Administration

I'm here.

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

Hi, Mitra. Stanley Crosley? Steven Keating?

Steven Keating – Patient Advocate/Consumer – Doctoral Candidate, Mechanical Engineering, MIT Media Labs

Hi, here, thanks.

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

Hi, Steven. And Terry Rauch? And from ONC do we have Mazen and Maya?

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yes, I'm here.

Mazen Yacoub, MBA – Healthcare Management Consultant

Hello, yes.

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

Hi, guys, thanks. Okay with that I'll turn it back to you Leslie.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thank you, Michelle, and welcome everyone, appreciate you participating. Today is really the first opportunity that we start to coalesce our responses, recommendations, talk over what we've heard so far and so it's an important part of our due diligence over the next few weeks.

As you hear information today and view the slides it is important to think about what are the gaps or things missing that we need to discuss, what are the accelerators that we would like to apply to certain areas and what are the opportunities that we might see that could help us advance our cause and I think there's a lot of moving targets going on and I think we've felt that as we heard testimony. So, today we'll begin to see some of that narrow in as we focus in on the cohort and the work at hand in 2016 and short-term, and near-term 2017 and beyond. So, let's go onto the next slide.

And these are all of our illustrious members, thank you for participating. Next slide, please.

So, the role of the initiative, again, is to accelerate opportunities for innovative collaboration, adopt policies and standards to support privacy and security of the cohort data, and advance standards that support participant-driven approach. So, these are our ongoing guidelines. Next slide, please.

So, we have heard a good deal from our federal partners about the PMI efforts that are going on today and starting to think about what is our role in helping to coordinate the data movement needed to support all of these partners in the initiative. It's a somewhat daunting task but I think we're getting there.

We also want to make sure that we're looking at new opportunities for use of APIs and using existing and future standards to help promote this initiative rather than relying on perhaps document-based exchange which is pretty much impossible with the volume of data needed and the data movement that will be necessary to support the cohort.

We also have heard about the different types of use cases to support interoperability and we'll do a little bit deeper dive on that today. Next slide, please.

So, this is our workforce, work plan and as you can see today we're beginning to see findings and recommendations, start talking about gaps, the next session, which Andy will lead, we'll begin to draft recommendations and then on the 19th we'll have recommendations going to the Joint Committee. Then beyond that we'll still work on finalizing our recommendations and then going to the Joint HIT Committee in May. So, it's a pretty accelerated timeline especially with a lot of moving pieces but I'm confident in all of your abilities. Next slide, please.

So, we looked at this initially, we said, we've got to get data from the lab to the EHR, from the patient to the EHR, from the EHR to research and the lab to the patient. All of these things may or may not be the same standards. We also note that because of the size and volume of this data the likelihood that this is going to be a simple interface exchange seems limiting for the genomic data itself, but using existing technologies and standards to move data that comes out of the EHR might be more realistic to do in that kind of a method. Next slide, please.

So, we heard from NCI and the FDA about the priority types of data that they need for this initial cohort imaging, lab, molecular characterization methods, pathology, radiology and so forth, therapeutic data including medication, diagnostic information and outcomes, as well as timed relapse, comorbidities, survival information.

And then pipeline with three steps with FDA focused on number two and three, how do we integrate information more fully from instruments, other software and clinical interpretation found elsewhere. Next slide, please.

The VA is looking for specific information like the Chemical Analysis Axiom MVP Biobank Array, that just slips right off the tongue, as well as the phenotypic information and domains that you see on the right. So, this information is going to be needed and the source of this information will be both the EHR, the lab, as well as the patient. Next slide, please.

We had some follow-up questions that we asked to NCI about what was their vision to include patient generated health data in their offering and they do believe that the cloud pilots are a foundation for a national database to house and integrate genomic information and outcomes information as a resource for scientists, healthcare professionals and patients, and this is primarily for research use like perhaps a citizen scientist and although they hope in the future, as you can see in the last bullet point, the patient specific data access is not currently in the scope for this knowledge-base, they hope that as a result of patient engagement being an important consideration that in future strategic planning efforts this would include patient specific data but that is not within scope.

So, this aggregate data is really for research and collection, and interpretation and testing against versus any specific data on this particular colab. Next slide.

We also asked the FDA about any sort of implied approval if people participate in the precisionFDA Initiative and it's clear that it does not, it doesn't imply any FDA endorsement, this is really about building a learning environment, initially using better tools and learning from that and how that can be applied in future efforts within the FDA.

They are also...we asked whether product testing results might be publically available and the intent is that they will publish that information and results on the precisionFDA Initiative and that the participants of the first FDA challenge are required to publish their comparisons. So, we will see data available more broadly from this initiative and I think that was one of our hopes as we asked this question. Next slide, please.

So, some things that are out of scope at the moment, but will be our work in the future, what kind of demographic data might be needed, are there opportunities to bring together people to determine what's the likely questionnaire type or vocabulary, or standards that might be needed to help make that demographic information clearer and more broadly standardized. Of course our bias is to use existing standards and vocabularies that are named but is there more that we need to do, things around race and ethnicity.

And then also, are there other types of priority demographic data for PMI? We heard from several of the organizations that they were gathering a good deal of information but there could be some similarities so this might be an area where we would recommend acceleration efforts to bring together a very solid questionnaire structure and vocabulary for patient generated health data.

And then the activities or pilots that ONC might lead in the future those will be part of future recommendations. And we also heard that the patient's rights and ownership of genomic patterned data is something that's largely discussed. What is our role in recommendations towards this. I think that still has to be discussed.

We do know from the White House meeting the President actually put forward his desire that this kind of data had inherent property rights to the patient that would imply some different use cases that we would deal with for standards and movement of that data. So, that was quite interesting but a future item. Next slide, please.

So, this is where we're going to spend a lot of our discussion and David I will try to describe a chart here but we've got the interoperable pathway to critical...that's critical to PMI.

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

Leslie?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yeah?

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

It's David; I've actually found a way to get on line.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Oh, perfect, okay.

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

But it would be helpful if you could use...say the slide number...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Sure.

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

In case I drop off because I have copies of the slides I just may lose my network connectivity.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Super.

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

So, you're on slide 12 right now, right?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

We are, yes, thank you for telling me.

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

Okay, I got it.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So, we're going to deep dive on each of these sections, but this is where the data flows that we need to work on and the sources and we'll talk about the timing as you see here. So, first a health provider organization the initial enrollment of that particular patient into the cohort, the next area is the patient generated health data, but from the EHR to the cohort information.

The third area is patient generated health data and this might come from multiple sources and we envision that this might be using a patient App or a device App that might be connected to the EHR through the API function and then made available back to the cohort. So, we'd like to use some of the newer technology recommendations for this and this is all near-term.

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

Leslie?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes?

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

Clarifying question?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Sure.

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

Is number two intended to describe the voluntary donor pathway or is that more generic?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

It's really more generic. This is...and Maya I'll ask you to speak up if I've got this wrong, but this is really patient generated health data that might be done directly from the patient to the EHR and going from the EHR to the cohort information versus patient generated health data that has not been integrated into the EHR that is sourced by the patient in other ways either through the device or the App of their choice.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

That's correct Leslie.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

All right.

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

So, it strikes me that the most useful patient generated data, and I think it was missing on your earlier slides, is actually going to come from the researchers who are looking at the genomic data, it won't come from the EHR at all. So, I'm thinking of the model that 23andMe uses for example...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

Where researchers can identify an interesting cohort of patients based on a genomic pattern and then send questionnaires to the consumers anonymously somehow but tied back to the genomic data somehow where they can ask questions that are relevant to what they're searching for because the chances of a relevant question just sort of randomly being in the EHR is pretty low.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Exactly and you make a really good point because we...in this slide we envision that the patient generated health data will come from multiple sources and we probably need to articulate both where it's within the patient's control and/or within control of other participants like the researcher who is getting that information where it's going to bypass the EHR and is going to bypass potentially an App controlled by the patient. So, we need to add that...

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

Right and...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

As a source.

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

Yeah and the direction of the arrows for that is a two-way thing. So, its questionnaires coming from the cohort that are probably technically from some other part and it looks like you called it a cohort, but from this slide it would have to be coming from the cohort to the patient directly. I mean, these are all implied, it's kind of one-way, downhill flow and I don't...I mean that might be where you get started but it's unlikely to be adequate.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

It is just...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yeah, David, this is Maya, I can just...just to pipe in, I think that we've separated this out into near-term and longer term considerations. I think what you're talking about is more of a longer term consideration, right?

So, that as you kind of can see the data in the diagram is flowing into the cohort as the initial first step and kind of what we...around 2016 but I think that the thing that you're talking about could definitely be maybe somewhere between number six and seven or like after seven, right? Like when we're talking...somewhere in there where we're talking about, you know, once there is an amount of data in the cohort that could allow researchers to start to identify those populations and ask those questions kind of the next step after this initial phase.

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

Yeah, no, I think that's exactly right. The reason I bring it up in the context of this slide is that there's not a lot of patient generated health data in the EHR today...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

And what's there is not likely to be all that relevant to the researchers. So, I'm wondering why we would put a lot of energy on that. I don't know...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yeah.

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

I mean, we'll have to see more what we think we mean by patient generated health data, but, you know, that's a...there's just not a lot of that and it's certainly not standardized...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

Today, focusing on the ability to deliver these questionnaires might be a much higher yield because then the standards are somewhat irrelevant you just ask whatever questions you need and get the answers and go forward you can...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

So, David, I think I understand your initial question.

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

Too much detail.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

No, no, no I think I now understand your initial question better. So, you asked does...for number two and three do we mean the individual enrollees and the data they will be bringing with them to the cohort, the answer is "yes."

So, for number two and three we don't necessarily mean patient generated health data like wearable, mobile and like kind of...you know there are different definitions and people think different things when we think of PGHD.

What we're talking about here is what the individually enrolling participant is going to bring with them to the cohort as discrete from what a participant that is affiliated with an HPO, like their data...

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

Got it.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Would just move automatically, yes, that's the distinction.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And I think where...

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

Yeah, that's...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Indicate on number two patient generated data from the EHR or the patient portal we're expecting that questionnaires could flow to the patient portal as another mechanism for input and then transmission from the EHR. But it's really then asking, back to your question, what's the intermediary device or system and it could be one that the researcher is actually saying "I'm asking questions, I have questionnaired the information that's PGHD that's got to go back in the cohort but it's not going to touch the EHR at all or the API." So, its worth, I think, having that distinction.

But you bring up a good point David the questionnaire work that has been done in the Standards Committee has been around the structured Consolidated CDA, patient generated data health header rather and also a questionnaire structure that just gets to an approach that would allow a questionnaire to be structured in a way that could be multiple choice, it could be yes/no, it could be any number of ways, it could be something that's geared towards decision-making of a patient, that has a much more gradient result, but that kind of standards work is still without any expectation of a vocabulary today, it's much more about getting a questionnaire response back into the record in a structured way. And I think we'd like to see that standard...a standard-based approach being used.

One question is, is there an opportunity in the near-term to look at any sort of vocabulary standards and is that necessary for that initial questionnaire for this cohort and if there is where would that happen.

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

So, Leslie, I'm...let me just obsess on this a little bit more.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

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

Let me ask the question, where on this slide is Sync for Science and the thing that takes the place once the pilot is over? I assume that's what you meant by number two.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

That is what we mean, yes, that's number two.

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

So, then you...that's not patient generated health data, that's patient volunteered...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

It's...

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

Access to their...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Patient...

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

Provider generated health data right?

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yeah.

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

Completely different thing.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yeah, its EHR data but it could also be, you know, other data that an individually enrolling person could bring with them, right, so it's not necessarily exclusive, but Sync for Science would be a part of that.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

I...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I would make sure...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

If I'm an individually enrolling participant I might bring my EHR data, I might bring my data from CDS, I might bring my data from my Fitbit, right? So, like there are different things in number two of which Sync for Science will be part. Does that make sense?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yeah, I think in our detailed slide we need to list what possible sources we mean under those titles...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

To make that clear.

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

Right, so...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

I thought there was a lot going on with slide as it is, but...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

We can add that to the more detailed one.

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

There is just a lot of difference between each of those pathways...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yeah there is.

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

And different technology, different standards and I think...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Totally agree.

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

PGHD is a misleading term in this case, that's my only point.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yeah, that's fine, that's fair.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

I will also note that for like four, five and six, you know, we still have, you know, lab, pharmacy and stuff there, that could be for an HPO participant or it could potentially be for an individual participant too.

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

Right, right.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

So, maybe we need to break that down a little bit more clearly, yeah.

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

Yes.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

This is Dixie could I say...can you hear me?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yes.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Go ahead, Dixie.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Oh, okay, okay. I think what you need to do...I think one, two and three are all really confusing and I think the reason is that the patient isn't...doesn't even appear in one and two, and in fact the patient is instrumental in all three of them. So, I totally agree with you that you need to provide more detail but I think the essential element you need to include in there is the patient.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I agree.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

I mean this thing about them completing a survey on the portal or whatever, not everything they put on the portal will ultimately make its way back to the EHR as structured data. So, I think that needs to be clarified.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

So, maybe we'll kind of say for number two, I think that's more important for two and three because for the HPOs the individual is less kind of involved in the actual transfer, the organization is going to handle that for them and they just consent to it.

So, for two to three maybe we say, individually enrolling participant data from EHR to...something like that, we'll figure it out.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

I think it would be useful to also show that the patient is the person who voluntarily says “I want to enroll” and I would not leave...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yeah, right.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

That out. I think that’s really an important point.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I agree, okay, we’ll work on that one and then in the next section you see as more medium term in four, five and six we’re looking at still getting lab data, pharmacy benefit data, as well as pharmacy data coming into the cohort.

And then the longer term is how do we return this data back to the patient and to the provider in an easy way or make available that data through query-based exchange to the patient and the provider in another way. So, let’s look at these more closely. Next slide, please.

Ketan Paranjape, MS, MBA – General Manager, Life Sciences and Analytics – Intel Corporation

Hey, just a quick question.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes?

Ketan Paranjape, MS, MBA – General Manager, Life Sciences and Analytics – Intel Corporation

Ketan Paranjape here, what happens with things like consent? I mean, is it already baked in that you don’t need an extra stage before that in terms of consent or is it just assumed that consent is built into the flow of data?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Nice segue.

Ketan Paranjape, MS, MBA – General Manager, Life Sciences and Analytics – Intel Corporation

Okay.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So, NIH is making some awards today to manage patient consent and transfer data to the cohort so we’re really looking at that consent happening at the health provider organization enrollment step as well as...it’s not as...it’s a different function but obviously if the patient self-enrolls that’s a different activity that would also incorporate consent. So, that work is being done for the health provider organization step and then...and I believe...haven’t those words been given?

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yeah...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes?

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

I'll chime in really quickly, so on February 25th one of the awards that we announced was the Director Volunteer Pilot that Vanderbilt is going to be leading. Ultimately, when there is a coordinating center awardee, which is to be determined, that entity is going to be managing all of the consent for the individually enrolling participants but for right now the Vanderbilt team is piloting and testing out some of those processes over the next year.

Ketan Paranjape, MS, MBA – General Manager, Life Sciences and Analytics – Intel Corporation

Okay.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And in this cohort all people will consent to participate...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Correct.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

It's not...it is not a situation where this is...it's a very proactive step and only those participants who want to participate and consent to participate will be participants.

Ketan Paranjape, MS, MBA – General Manager, Life Sciences and Analytics – Intel Corporation

Okay, well, thank you, because the other question also is in the degree of consent, if that's the right term, that, you know, I don't mind sharing my labs and imaging data but I do not want to share my genomic data.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

Ketan Paranjape, MS, MBA – General Manager, Life Sciences and Analytics – Intel Corporation

And then of course mission readable consent and all that jazz comes into play. I'll take it off line with the Vanderbilt folks, thank you.

Gil Alterovitz, PhD – Faculty, Center for Biomedical Informatics – Harvard Medical School; SMART/FHIR Genomics Lead

I have a question actually on the previous slide, so in terms of a genomics I can see that being in the first block or potentially in the second block, or both just wanted to get a clarification on that.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yeah, so for genomics I think it's actually probably going to be...I don't know for sure to be honest, I can tell you that for the Director Volunteer Pilot that Vanderbilt is doing the initial data that was in that kind of scope of work will be patient self-reported data through surveys and some medication data, also patient reported. So, they did not contemplate testing the flow of genetic data at this time. I assume it's something for like 2017, 2018 so in that last bucket of time, but I cannot be totally sure.

Gil Alterovitz, PhD – Faculty, Center for Biomedical Informatics – Harvard Medical School; SMART/FHIR Genomics Lead

Yeah...

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

Are you talking about...

Ketan Paranjape, MS, MBA – General Manager, Life Sciences and Analytics – Intel Corporation

I was...the part of number three maybe, because 23andMe becomes a multiple...you know one of the sources through an API getting piped into this, that just SNPs I know but...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

No, that's a really great point, I just don't know if that is going to be able to take place in 2016.

Ketan Paranjape, MS, MBA – General Manager, Life Sciences and Analytics – Intel Corporation

Exactly.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Because we've kind of bucketed this by time, but you're correct like in that workflow you certainly could do that eventually as long as the...

Gil Alterovitz, PhD – Faculty, Center for Biomedical Informatics – Harvard Medical School; SMART/FHIR Genomics Lead

Yeah.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Coordinating center is set up to receive that, yes.

Ketan Paranjape, MS, MBA – General Manager, Life Sciences and Analytics – Intel Corporation

Okay, yeah, but the patients...

Gil Alterovitz, PhD – Faculty, Center for Biomedical Informatics – Harvard Medical School; SMART/FHIR Genomics Lead

Yeah that's what I was wondering because it could be...

Ketan Paranjape, MS, MBA – General Manager, Life Sciences and Analytics – Intel Corporation

...

Gil Alterovitz, PhD – Faculty, Center for Biomedical Informatics – Harvard Medical School; SMART/FHIR Genomics Lead

Yeah.

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

But isn't the...I mean, the coordinating center assumes the tissue is actually being collected for...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Right.

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

New de novo genetic extraction right?

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Well, there's a separate bio-bank award actually which is discrete from the data coordinating center award...

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

Right...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

So, that...

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

But...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yeah, yeah.

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

The whole thing is predicated on deep sequencing, I mean, so, I don't know...I mean, separate award is a bureaucratic issue not a...I mean, that's still an incredibly important flow of data, right, that the tissue has to get...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yeah, it is, it is, I think, that we are not going...I think that's outside the scope of this particular work that we want to accomplish in the next couple of months...

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

Right.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Just given the time, but again, yes, absolutely, like that is...it's definitely going to be part of the overall PMI landscape. I think just in terms of the scope and, you know, the narrow focus of this group we wanted to concentrate on things such as medications, labs and the data that you can pull from the EHR.

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

Yeah, so this is all phenotype data basically.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Right, correct.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Correct. So, I think that Maya it would be worthwhile to have some sort of chart that indicates where all the moving pieces are with the awards, the databank, just a big ecosystem picture that we can get an idea of.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Because I hear...I'm reminded of a comment that David made, I think several meetings ago, when we were hearing about Sync for Science and we were hearing others, it was...he asked a question that made it very clear that the particular group was...had a bias for existing standards and was looking at that, but brought up a question where it did make them rethink their gaps that they might have considered in those standards because of that input.

So, this group might be able to see, by looking at that ecosystem, where are the natural places where standards need to be synchronized across these efforts so that we can provide some good input to that, because they might not be obvious or top of mind. So, let's work on that for our next meeting.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Great, that sounds good and yeah, probably it's best to have that come directly from NIH, yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay, super. So, let's go onto the next slide. So, in that first area I think we've talked about the health provider organization and how they'll do enrollment and facilitate that exchange including the consents and so some of the things we talked about is, what are the minimum datasets, the standards and the APIs that might be used and this is a common theme that you'll see on each of these slides.

So, this is an area of our work to say, what do we think the scope of these things are and are there gaps that also need to be discussed? And Maya we have a grid further down in the slides I think that will get to more detail. Are there other considerations that we would like to see in this pathway...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yeah, I'll just point out one quick thing...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Concerns or opportunities? Yes?

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

One quick thing that has come up in our discussions with NIH is the use of the PCORnet data model, oh, I just lost connectivity on my webinar by the way, so, anyway...the common data model that PCORnet has kind of used and promulgated, if folks have thoughts on that I think that would be appreciated.

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

Okay, this is David, can I ask a question, is the thought that our Task Force is going to make recommendations that would apply to the coordinating center awardee or does the...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

No, not specifically...

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

Awardee get...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yeah, not so specifically. So, like the...we can't assume that the recommendations of this group are going to be implemented by that awardee because obviously it's a grant and we have limited, you know, control over what these awardees do and plus it's an NIH, you know, thing.

I think the goal of this is more to identify certain areas, you know, NIH and whatever eventual awardee will need to be aware of, so are there gaps, are there issues, are there, you know, best practice standards that we want to kind of identify and put in place for each of these different workflows that we've diagrammed out, just, you know, to help educate and keep them aware of what issues they're going to run into as they move through implementation. Does that make sense?

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

So, these are...sort of these are friendly suggestions or...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Closer to that.

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

Yeah, okay.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And there seemed to be very open recipients.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yes, yes, I agree.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And want to make sure that they are doing something that can be done to scale. So, this...I think these are friendly reminders but with a friendly recipient as well.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Correct.

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

Yeah and my only reason for bringing it up, and, you know, full disclosure, we're competing to be the coordinating...competing for the coordinating center grant, is that most of those folks are deeply knowledgeable about this space. I mean, it's not like they've never heard of CCDs or...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

LOINC or anything like that. So, I was trying to just clarify what we bring to that discussion and, you know, a friendly suggestion is a good starting point. Well, when we get deeper into it we can figure out how useful that is.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I also think David if we think there's areas that could be facilitated by convening or accelerating methods to help drive more standards across this I think we can make recommendations to that effect too, what kind of process might be used to help that awardee to have a more broader view.

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

Yeah, good, thanks.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

All right, so, next slide, please. I think we've talked a little bit about that, we do need to be more explicit about the patient in this question and also to make sure that we outline a few more of those data sources as we discussed earlier so that this is clear to any of the audience reading it and also it identifies the potential complexity that this might bring.

So, as we go forward we've talked about the standards that are coming forward out of the API Task Force and FHIR, we've also talked about Consolidated CDA. The group has said, we have a bias to use existing standards that are already named within, and I don't see any conflict there, the gaps that we have today are really around vocabulary in any sort of standardized questionnaire for phenotypic data and that may be an area that we'd like to make recommendations towards for acceleration efforts.

There was a...at the meeting...one of the breakout meetings at the White House event NIH was very receptive to that idea of having a...is there a top 100 that we need to build around questionnaires that would have vocabularies associated with it by bringing a small group of people. So, that could be a recommendation that we have. Are there other ideas for this area besides what we've already mentioned?

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

I have one...

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

So, just...

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Topic that...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes?

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

That I've been working on in my...this is Dixie.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes?

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

I heard just a while ago someone asked about what data model they're using whether they're using the NCI data model, the PCORnet data model. I happen to be right now in a process of mapping the PCORnet common data model to the FHIR DSTU2...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Wow.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

And it's not just vocabulary it is also that the data elements are not always even there. The data elements that are in the PCORnet CDM are not always in the FHIR resource definition. I suspect the same is true if NCI has its own data model. I think it's important to know what they will be transforming the data to, what data model they're transforming the data to in order to figure out whether what we're providing them is sufficient. Does that make sense?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

It does and so if you were to wave your magic wand to have that work being done how do you see that happening and where?

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Well, the first step is figuring out what data model they're using.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

I mean, the PCORnet data model is based on the FDA Sentinel Project...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

It's not based on NCI. So, there are even differences between those two just as an NCI initiative so I imagine they're using their own data model. But that process of looking at the resource definitions and the elements and the data types that are associated with the elements and mapping that to what they will be getting from the EHR is really important and I would hate to see all of them, you know, everybody having to do that individually. I think the project as a whole needs to do that.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yeah...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

...great.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

That's a great point. Can we make a note of that Mazen to kind of explore that and then one quick correction or clarification I wanted to add is, actually this is not...PMI is not an NCI sponsored project, it's actually broader than that.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Right.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

So, I just wanted to make sure that this was not an assumption.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

I know there is...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I just don't think this can be over emphasized because this is Greenfield work.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Why not do this now instead of simply the same old same old where we automate hell, let's try to do this work now and that might be a great area for acceleration or convening a group to do that in the very near-term.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

It is...

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

So, this is David, I want to...

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Part of the...

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

Piggyback on that idea, Dixie and I have actually talked about it off line, but, you know, so the Argonaut Group is trying to put some profiles together for the FHIR resources that we think are sufficient to meet the 2015 edition certification requirements and it's also a pretty good start. There is good vendor participation. It's hard work even getting vitals...even getting blood pressure has proven to be a real challenge as anybody who has ever tried to do that knows, but it looks good.

There is also this thing called the Data Access Framework Group that used to be an S&I Group, I'm not quite sure what auspices it's operating under right now, but they're looking at augmenting those FHIR resources for the PCORnet data model that Dixie described.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Oh, I didn't know that, okay.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

This is why we have these calls.

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

Yeah and I'm not...I'm not quite sure of all the details, but, you know, the goal would be to think of extensions...well, you know, an ideal goal would be to say if the data is so important that it belongs in clinical research databanks then maybe it really ought be a part of the core FHIR resource itself, but the mechanism you deal with that in the short-term is you create an extension to FHIR. So, for example gender and ethnicity are extensions to FHIR because they're only relevant in the US.

So, a set of research extensions to FHIR that would be driven by the needs of PCORnet and ideally precision medicine would be, you know, kind of the next best step and the reason, you know, to think of that as an important goal is in the long run we'd like to have the vendors when they export data for research to be able to do it in a standard way. So, instead of everybody dumping their data model out...

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Yeah.

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

In vendor specific raw form map it to FHIR and dump it out that way and that will take some time, a long time probably but we need to start on getting those resources defined, you know, sooner rather than later.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

David's right...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Can...

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

It really isn't new resources it's really for the most part, in many cases, its new data elements that could possibly help in healthcare as well. So, that whole work is really important to not forget.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Can I also...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And so Maya...

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

Yeah, no...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Sure, who was that?

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yeah, sorry I was...

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

This is David, I...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Oh, go ahead.

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

Go ahead, go ahead.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Go ahead, David.

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

Well, I was just going to agree with Dixie that it should be an extension to a resource not a new resource. A new resource would be a very bad idea.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Right, but maybe not even an extension, it may be part of the core, as you mentioned earlier; it might be part of the core resource.

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

Yeah, yeah, yeah, but then that would require DSTU3 or whatever...

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Yeah, yeah.

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

Before those statements could be made.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Yeah, right.

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

Right.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Yes.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

There was another...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Just to clarify...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Question?

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yeah, just what we've heard thus far, I wanted to make sure that I am clear on what all is going on. So, Dixie mentioned she working mapping the PCORnet data model to FHIR resources but that is apparently a separate effort from the DAF effort to map the PCORnet data model to FHIR resources, is that correct? Did I hear that correctly?

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

I sure...I didn't...this is the first I knew about that but if I can get some answers from them that they...I certainly don't want to duplicate any effort. So...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Okay, no, no, no, no problem. I think what we can do...because I think the DAF work is being done under the auspices of a PCOR project that ONC is leading. So, Dixie, why don't we take that off line and I can add you to that.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Yeah, that would be great, yeah.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Okay, great.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And beyond that Maya though the other point that David made was the NCI and also the EHR data models how do we align all of that so as we're not replicating work. And I think not only what's the best way to accelerate and to do that work but at what point should that be inserted into the larger ecosystem. Is this something that is done before the coordinating group is awarded, after that, as they're part of it? So, recommendations I think around both mechanism and timing would be important to hear from staff to this point.

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

And just to add to the alphabet soup, I think DAF can say all they want and others can say all they want but the code that's actually getting written today by the vendors it through the Argonaut process. So, you know, probably even more important to try to synchronize any deltas with the Argonaut Groups. The sync...

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Yeah, just for FYI, we have Josh Mandel on the agenda for our next meeting of the PPRN PIs to do exactly that, couldn't agree more.

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

Yeah and the Sync for Science that Josh is leading is based on the Argonaut work. So, I mean...

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

But he'll be talking, right.

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

Yeah, so, just that's another one. I mean, there's too many talking heads.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Yeah.

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

But, it's the way it is.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

That is the way it is, but, this is too important to kind of let that go un-shepherded because we'll just end up with the same sort of fiefdoms and silos, and lack of standards if we go forward with that. So...

Mitra Rocca, PhD – Associate Director, Medical Informatics – Food & Drug Administration

This is Mitra, sorry.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes, Mitra?

Mitra Rocca, PhD – Associate Director, Medical Informatics – Food & Drug Administration

This is Mitra Rocca from FDA, actually a few years ago I had to map the Sentinel Common Data Model to OMOP which is now OHDSI that is Observational Health Data Science and Informatics that is another group that has a similar initiative too on FDA Sentinel Initiatives and this Friday...and they also map their common data model to PCORnet. And this Friday I invited them to present to CTSA at the NIH to our Informatics Advisory Board on the awards that we have done on mapping these different common data models.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

That might be something that would be useful for this group to see.

Mitra Rocca, PhD – Associate Director, Medical Informatics – Food & Drug Administration

Okay.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thank you so much.

Mitra Rocca, PhD – Associate Director, Medical Informatics – Food & Drug Administration

You're welcome.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay, any other comments here? We'll go to the next slide.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Yeah, who was just speaking?

Steven Keating – Patient Advocate/Consumer – Doctoral Candidate, Mechanical Engineering, MIT Media Labs

Sure.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes?

Steven Keating – Patient Advocate/Consumer – Doctoral Candidate, Mechanical Engineering, MIT Media Labs

My name is Steven Keating.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Hi, Steven.

Steven Keating – Patient Advocate/Consumer – Doctoral Candidate, Mechanical Engineering, MIT Media Labs

I'd like to just make a quick comment here.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Sure.

Steven Keating – Patient Advocate/Consumer – Doctoral Candidate, Mechanical Engineering, MIT Media Labs

So, yeah, I'm just curious about...so all the arrows are all just going to the right, towards the PMI cohort and I know...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

Steven Keating – Patient Advocate/Consumer – Doctoral Candidate, Mechanical Engineering, MIT Media Labs

That's in, you know, the number seven on your screen was return the patient data but I know that was 2017 to 2018, but I think it's really important to note that as soon as you're asking people to consent and donate data that they'll be wondering what they're getting back. And so I think it's important to have recommendations of what is the arrow coming out of the PMI back to the patient and to other research groups looking like and what are some of the different regulations and policies that we can clarify around it such as, you know, is CLIA data, you know, is the research data available to patients if it's not CLIA certified...CLIA certified...or can a patient click a button and say "yes, I'm willing to make this open or not."

Can we have...to make sure that what is the incentive that is being shown to the patient for steps two and three to make them want to participate, you know, is there...can they at least have satisfaction of, you know, being listed with their name on the website that they may have contributed or could they have access to their own information or can they press a button to say "yeah, I'm happy to share my information."

So, I think it's really important that we don't just keep the return to patient data stuff for 2017 and 2018 but as soon as people are submitting data we should have some type of policy, suggestions of what they'll be incentivized to get back.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And that's a really good point Steven because there is a quid pro quo expected and how do we...how do we facilitate that in a timely way. So, I think it's important to note what our role is.

Steven Keating – Patient Advocate/Consumer – Doctoral Candidate, Mechanical Engineering, MIT Media Labs

Right.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Because this Task Force is really not...we're the how versus the what. So, NIH will be looking at this. I think that what we want to emphasize is that we believe that the...and we'll respond to an earlier date as directed because we do feel it is important. And so as we consider this work then we may be asked to move earlier or sooner on that arrow because of the interest, because of, I think the momentum and simply because the patient will want to know. So, as we know when this...or what is needed then we will respond and I think, so noted we'd like to see that sooner than later but not within our purview.

Steven Keating – Patient Advocate/Consumer – Doctoral Candidate, Mechanical Engineering, MIT Media Labs

Great.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Other comments? Okay, next slide. So, now we're looking at in 2017 the lab information that will be coming into the cohort, where the individual is enrolled and may eventually try to supplement the EHR data with data from the lab information system. So, I think this gets to the same questions we had before, are there other efforts or efforts going on right now that we see ongoing for this data that may need to be coordinated, do we see anything that would need to be done this year in order to facilitate a 2017 response, what are your thoughts?

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

So, the big challenge here is going to be identity matching for purposes of authorizing the release from the labs. If you get the data through the EHR then that will have already been done, but getting it directly from the labs is pretty challenging.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Although the labs have been doing...I know LabCorp for instance is the back end to 23andMe and I know they have been doing remote patient authentication and ID work with about a 95% accuracy rate to identify the patient themselves to the lab. The identity matching and back to the cohort, you're right, that is a whole different ballgame that needs to be considered. So, that might be an area that we suggest, in order for a 2017 determination of this, there has to be some work being done on identity matching.

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

Well, how much data do you think is going to come from the labs that you don't get through the EHR? Is it a substantial amount?

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

I think...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

What I...go ahead Maya.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Genomic data there will be a lot.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes, there will.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Yes.

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

What was that? Say that again, I didn't hear it?

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

For the genomic data, the whole genome sequences will most likely come from the labs directly.

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

Well, yeah, but I thought that's why the tissue submission was so important. I don't...I mean, do you honestly think there are going to be that many places that are going to...there are labs that have whole genome data that they're going to submit? That just seems really a stretch.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

So, when I, so when...

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

For exome or even variants that matter.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yeah, we had not...we were not planning to focus on genomic data for number four.

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

Yeah.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

We were...yeah, we were not, that was not supposed to be the focus of it.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

But in the recommendations or the datasets that both NIH and FDA looked at needing, additional information was coming from the lab. The question is how much of that would be coming outside the EHR that might be...I'm trying to think, it might be minimal or it might be multiple labs, but it might be commercial labs versus just hospital labs. It might be worth discussing this a little bit further.

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

Yeah and it's David again, what I was thinking is that at least in, you know, I suspect most EHR settings there's an interface to the lab so that the lab order...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

The results come back to the provider's EHR, but certainly it's not 100% true, sometimes the labs come back just as a faxed piece of paper. So, yeah, I guess there could be...you could end up with quite a bit of data that you can't capture through the EHR feeds.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right even a hospital acting as a commercial laboratory may not be feeding that data back to their own EHR but feeding it to the ordering physician at their clinic. So, the...

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

Well, so, what that raises is the much more thorny problem that the patient's record is highly distributed and the likelihood, you know, in the near-term of getting a complete record is pretty low simply because everybody...you'd have to have a portal at every one of your doctor's offices you'd have to authorize those portals every one, keep track of it, that would be, you know, beyond the pale for anybody other than the most diligent volunteer donor. I mean, most people don't do that for their own health data much less to donate to research. So, in that sense the lab as an aggregator does make some sense, but you're back then on the identity and authorization issues.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So, that would be something...

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

But I just...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Maya we'd like to put forward as a requirement prior to this...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yes.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Is the whole identity matching issue and the assumption that with a distributed record information coming in, the whole identity matching record locator service is a precursor to this.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Right, yeah and I think...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And I'm sure we can build on work already being done.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yeah, absolutely, and I think to the extent that we want to maybe add something in here just to say, like check out this existing work, you know, like we can list a few options in terms of further research.

And then the other thing I wanted to say is David's point about, you know, how distributed the patient's data is across so many different sources is very well taken. I think as an introductory point to the final recommendations of this group we should probably have that at the very top, you know, like this is the state of affairs given that we are exploring all of these different, you know, we urge the exploration of all of these different data sources in order to come closer to achieving a complete record even though we realize it is going to be really difficult to do so for each person...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Can we...

Gil Alterovitz, PhD – Faculty, Center for Biomedical Informatics – Harvard Medical School; SMART/FHIR Genomics Lead

This is...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Go ahead, David.

Gil Alterovitz, PhD – Faculty, Center for Biomedical Informatics – Harvard Medical School; SMART/FHIR Genomics Lead

Oh, sorry, yeah, hi, this is Gil, yeah, just had a little addition to what David was saying, I think...so one thing that maybe useful to consider then is to recommend one approach that...like one standard that is the same across the labs, EHR and portals, you know, for example 23andMe and others, so that no matter where it comes from, you know, they'll all be with a consistent FHIR-type API so it's kind of more transparent in that way so that maybe one way to think about it.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

That's a great idea. Can we go to the next slide?

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

Gil, that's...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I have a question that is related and Surescripts has made a commitment to support PMI and Surescripts services is not just the pharmacy benefit management or the medication history but also the National Record Locator Services and so I'm wondering if this is an opportunity to learn more about this and the identity mapping, and record locator services that are provided as a result of this commitment.

Claudia Williams, MS – Senior Health & Health IT Advisor – Office of Science & Technology Policy – White House

Hey, this is Claudia on the line. We're actually...I'm not certain that this part of it isn't going to end up being a big service immediately because they're just piloting that service right now. So, I think the Surescripts work will focus on that history at least for the near-term.

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

And...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

I would just add like if we could look at this more broadly than just Surescripts like...

M

...

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

Yeah.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

I think we're talking...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Sorry, can we go to one person at a time, who was just mentioning the Surescripts?

M

Here or...

Claudia Williams, MS – Senior Health & Health IT Advisor – Office of Science & Technology Policy – White House

This is Claudia.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And everybody mute.

M

...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Oh, yeah, I think there is somebody just talking in the background he is not on mute.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

So, this is Maya, one thing I wanted to mention is we don't want to limit this just to Surescripts. I think what we wanted to do is explore, you know, if we were to get data from any PBM what would the issues be, what would the standards...you know just make it broader than that. Surescripts is an example, an illustrative example but not the only thing to consider here.

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

Yeah and this is David, you know, I'll throw out the thought that, you know, Surescripts as a record locator service is not a live service and they, in many cases, don't have permission to use the data for that purpose, they have to use it for ePrescribing but not for research, donation, record location and so forth.

CommonWell is another one that you should put in...rope in because CommonWell does have a live record locator but even there I'm not sure that the enrollment process would, just by default, allow for this use case because it's not HIPAA direct treatment. So, you know, using this data for purposes that go beyond HIPAA direct treatment is going to require additional consent I think from anybody.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

But it does highlight the need of a record locator service and identity management and also highlight or illustrate that there are multiple sources for this, and I think your point on CommonWell is a good one, and so we need to make sure that where they're isn't a contract in place to do these services we are mindful of the opportunity that this might bring to multiple organization's solutions.

But that being said it's back to the earlier point, I think was that Steven who made, how do we make sure that these efforts are coordinated as we mentioned earlier on the PGHD because so much will ride on the ability to do identity matching and record locator services, how do we identify the dataset, is that going through...or initiating or building...following up on the back of something in an Argonaut Project, is that someplace else. So, appreciate thoughts there as well.

Claudia Williams, MS – Senior Health & Health IT Advisor – Office of Science & Technology Policy – White House

This is Claudia and I missed a few minutes, I apologize if I missed something, I guess I would encourage this group to think about layers that are confirmed. There are a lot of ways you can imagine building out the various things that you need, and maybe Maya you can provide guidance here too, but I'm not certain that a record locator service is going to be necessarily something that NIH needs. Certainly they're going to have to do matching within their own system and as they have data coming in, so that seems like much more likely to be needed.

So, just wouldn't want this group to focus on things that are sort of hypothetically needed but maybe not needed, but maybe Maya has additional guidance there.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Maya?

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Sorry, it's a little hard to hear you Claudia, what was the question? There was like some background noise, I'm sorry.

Claudia Williams, MS – Senior Health & Health IT Advisor – Office of Science & Technology Policy – White House

I'm in a car so I don't know if anyone else could hear me better. I was just not sure that a record locator service was something that was going to be needed by the cohort and would want this group to focus on things that are like, you know, almost for sure needed.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yeah, right, right, so we had not...I mean, I think this is something that we could put in the parking lot. So, we have a slide I think later in the deck of issues that, you know, we are seeing here in terms of patient match and finding a patient's records across multiple sources. I don't know that we need...given again like the very short timeframe that we have for the rest of this Task Force...I mean, maybe Leslie and Andy I would leave that to...you know we can take it off line and think about what we think can be in scope for this and what should be out of scope, but I tend to agree that it's something to explore later.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Although, I mean, if people have like suggestions and we want to collect them of like future things that we could look at if we do...you know in a future phase of this Task Force, you know, we could get those ideas started and parked there, you know, but we don't have to resolve all of that right now.

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

So, this is David, I think there are a couple of issues then that need to be just tracked forward, one is the coordinating center grants do assume that the MPI work would be done by the coordinating center so I think that...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Right.

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

You're correct, Claudia, that you don't need to solve the MPI problem before this stuff can work. On the other hand, if its consumer donated data the incompleteness of it needs to be accounted for just because the patient might not know or care, or wish to use all their portals to pull their record together. So, you know, you may have valuably donated data but it could be considerably incomplete. So, I think those are just two separate points.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

That's a good point. So, let's go onto the next slide which is really just a recap of...oh, I'm sorry, I forget about that, pharmacy. Pharmacy data was also indicated as a top priority for NIH to get the data. It's the same question of the labs the things that might not be found in the EHR but available through other pharmacies or through the pharmacy benefit manager and this is an area that I think has more maturity than other areas, pharmacy information in general, because of the infrastructure in place with pharmacy benefit management organizations or infrastructures like the Surescripts and others. So, are there thoughts here or considerations, or opportunities for acceleration?

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

This is David, I think some of the same concerns apply, you know, do PBMs do data feeds to large entities that, you know, sweep up an Accountable Care Organization or something like that, I'm not sure that they do patient specific single shot APIs. And then, you know, they would obviously only be able to do it if they had some proof that you were in fact authorized to release your data.

So, again, to the degree that you can get this data because it's already been accumulated in the EHR that helps a lot. That doesn't include dispensing data typically in some EHRs...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

It does, but not always. But, so I think the issue is not so much is the data there. The data is there but what are the channels that you have to get access to it. So, that's probably challenging still.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So, maybe what we should do is rethink on these near-term, medium term and so forth is there is really the initial data that is coming from the EHR of the type of lab, the pharmacy information and such, the imaging information that we saw earlier as one area of requirement and focus on that as the near-term, so a broader range of data but when using the EHR as the intermediary can be retrieved in a near-term form and the longer term, which would be the independent lab, independent pharmacy, independent imaging center record would be more of that medium term effort. Does that seem reasonable?

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

This is David, I think that makes...that expresses it nicely Leslie, that's I think exactly sort of what we've been bumping up against. I mean, you know, the irony is we can't do these data flows for the sake of patient care today at scale...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

Why do we think we should be able to do it for a research grant, right? I mean...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yes.

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

This is the dilemma of interoperability writ large, we don't do this well anywhere yet, well enough, I mean we do parts of it but not all of it.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And actually by focusing on the EHR data and maybe the patient generated health data coming through the EHR as well in its initial phase we have an opportunity to move to scale many other initiatives because we would be focusing on that and that data coming from the EHR to the cohort. And you know it would...high tides rise all ships, whereas...

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

Yeah, I just...I just don't know if the tail is going to wag the dog or the other way around.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yeah, right. Maya, what do you think about that approach? Oh, she lost her Internet so maybe she lost her audio as well. Maya? Okay, we'll take that off line in other discussions, but I think that might be another way to stage this in a more reasonable way and stay focused and more on the immediate needs of the cohort that way.

So, we have...are there other items...so we've talked about now, next slide, please, we've talked about the long-term goal of getting information back to the patient but back to the point earlier we would really like to hear from NIH on the work they're doing here so that we could help accelerate this effort through recommendations and standards to get the information back to the patient. I think that becomes a high wish list although not within our purview we would like to support accelerating that effort. Is that a good way to put that? I think Steven that was your initial request as well.

Steven Keating – Patient Advocate/Consumer – Doctoral Candidate, Mechanical Engineering, MIT Media Labs

Yeah, absolutely and I think there could be a couple of easy routes to try to suggest that...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

Steven Keating – Patient Advocate/Consumer – Doctoral Candidate, Mechanical Engineering, MIT Media Labs

One could be just having an API from the PMI that is accessible to patients so that even if it's just a very simple API that basically the patient has control over for third-parties to develop on. So, with that...and it would just be accessible just to that patient's own data so there would be no ability to kind of, you know, share with other people but as a starting point then at least the patient can see what they've, you know, put into the PMI cohort and it adds at least a very small incentive there is that notion that "hey, look if you contribute your data maybe if you're traveling somewhere there is always a way for you to access it or you can download this fun App and you can do this and this, and this."

And so I think if we can try to like, you know, suggest these kind of simple ways that aren't too far down on the boundary line of, you know, accessing other people's information, start with just with accessing yours and at least that will start the ball rolling.

And then I think a second route would be to start working with some of the groups who are pretty good at this already such as PatientsLikeMe and Open Humans, and the Personal Genome Project and just have a dialogue and see, can you connect these patient-facing groups to the PMI so that, you know, you can connect...if you look at Open Humans they have, you know, thousands and thousands of members, the same with 23andMe if you can connect them directly to the PMI you'd have another large data source and then you have a patient-facing interface to it. So, I think those two would be an interesting starting point.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

Steven Keating – Patient Advocate/Consumer – Doctoral Candidate, Mechanical Engineering, MIT Media Labs

And maybe one other third point just also on the policy side of what does HIPAA mean and what does CLIA mean, and what does CommonWell mean? Because there are inherent policy conflicts on that, you know, there...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

Steven Keating – Patient Advocate/Consumer – Doctoral Candidate, Mechanical Engineering, MIT Media Labs

Are certain types of data if it's not done on a CLIA certified machine that providers will think they cannot give back to patients and we need better clarification on that, we really do.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Great, I think that's a good recommendation. So, I'm going to ask if Maya, have you been able to join back in?

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yes, hi, I'm so sorry, I don't know what happened with my phone.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay, so, that's all right. So, what was discussed earlier, and I'm not sure when you logged off, if we could just go to the next slide really quick and then come back to this, was that a way of staging this rather than looking at all of these data sources in this kind of sequential effort is saying we have a bias initially to use data that's been staged through the EHR rather than this fragmented approach that will require us to go to individual labs, individual pharmacies and so forth or individual clinics that might be a more longer term ask and that way we could get a richer discussion, faster acceleration on more types of data where the EHR is the intermediary. I think that might be very helpful.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yes.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I would also suggest that the patient generated health data that's coming from the patient be considered in that upfront discussion. And then, if you could go back to the previous slide, we talked a little bit about the patient access to this information and although that work is being done by the NIH there are some design considerations that could be talked about in the actual enrollment phase so in the enrollment phase of the patient we now have, where they're volunteering themselves to participate, we have an identity of that patient now, we have a record of that patient, we have information that would allow then for an App at a future date to be able to know that this individual patient is coming in for their information.

So, just to consider in the consent process and enrollment process mechanisms that would allow for the patient to access their own specific data in a timing to be determined but with a bias for this group to say “hey, we’d be happy to work on that earlier than later because we think that there is opportunity.”

Then also Steven made recommendations that we consider learning from the more commercial providers, as we have heard from 23andMe, to take any learnings that can help us in their interactions with direct to consumer and Steven did you have a third point as well?

Steven Keating – Patient Advocate/Consumer – Doctoral Candidate, Mechanical Engineering, MIT Media Labs

Yeah it was kind of just, one is allowing an API to come out of the PMI so that we can have third-party developers...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

Steven Keating – Patient Advocate/Consumer – Doctoral Candidate, Mechanical Engineering, MIT Media Labs

Write their own Apps that patients can download and consent with just their own data so not talking about other people’s but as a starting point allowing third-party developers to actually be able to use the PMI data so that people are incentivized to contribute to PMI. And then the second point, as you mentioned...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yeah, yeah I like that.

Steven Keating – Patient Advocate/Consumer – Doctoral Candidate, Mechanical Engineering, MIT Media Labs

Yeah, the second point, as you mentioned, looking at a lot of the commercial models, so 23andMe, PatientsLikeMe but also a lot of the non-profit stuff like the Personal Genome Project and the Open Humans.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes.

Steven Keating – Patient Advocate/Consumer – Doctoral Candidate, Mechanical Engineering, MIT Media Labs

I mean, right now Open Humans has a new API on it so if you actually donate your data to Open Humans you can submit it to the API and any third-party developer can then create an App that you can use. So, I would love to see that also in the PMI. And then...

Gil Alterovitz, PhD – Faculty, Center for Biomedical Informatics – Harvard Medical School; SMART/FHIR Genomics Lead

So, I’ve an...oh, go ahead, sorry.

Steven Keating – Patient Advocate/Consumer – Doctoral Candidate, Mechanical Engineering, MIT Media Labs

Sure, go for it.

Gil Alterovitz, PhD – Faculty, Center for Biomedical Informatics – Harvard Medical School; SMART/FHIR Genomics Lead

Oh, no, I was just going to support what you said and just add that right now a number of these different portals have their own different APIs.

Steven Keating – Patient Advocate/Consumer – Doctoral Candidate, Mechanical Engineering, MIT Media Labs

Right.

Gil Alterovitz, PhD – Faculty, Center for Biomedical Informatics – Harvard Medical School; SMART/FHIR Genomics Lead

And it would be nice if, as we made a recommendation to support either FHIR or some standardized way so that...because we see a lot of standardization toward getting the data into the PMI but it would be nice if there is a standard way of getting it out for the patient and provider to create these Apps so that they would work for different patients, you know, on their own data but they could use the same App and not...and it wouldn't be dependent on where they got the...you know where the data was from.

Steven Keating – Patient Advocate/Consumer – Doctoral Candidate, Mechanical Engineering, MIT Media Labs

That makes...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So, really what we're suggesting is that any data that goes back to the patient is using a standards-based API just as we're working on today from the EHR and that we are consistent with that work.

Gil Alterovitz, PhD – Faculty, Center for Biomedical Informatics – Harvard Medical School; SMART/FHIR Genomics Lead

Correct.

Steven Keating – Patient Advocate/Consumer – Doctoral Candidate, Mechanical Engineering, MIT Media Labs

Yes.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And that we encourage that any necessary identity matching or that would require or allow a patient to connect directly to that API be considered as part of the design principles when the individual enrolls so that we've got a circle from the very, very beginning.

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

A...

Gil Alterovitz, PhD – Faculty, Center for Biomedical Informatics – Harvard Medical School; SMART/FHIR Genomics Lead

Right.

Steven Keating – Patient Advocate/Consumer – Doctoral Candidate, Mechanical Engineering, MIT Media Labs

Is...

Gil Alterovitz, PhD – Faculty, Center for Biomedical Informatics – Harvard Medical School; SMART/FHIR Genomics Lead

I think that was a consistent theme that we saw going kind of completing the loop so that it's not just one way but it's two ways and then it's connect the loop.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

Gil Alterovitz, PhD – Faculty, Center for Biomedical Informatics – Harvard Medical School; SMART/FHIR Genomics Lead

Exactly.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes.

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

So, this is David, a couple of comments on that, one is just a technical thing on this slide that we're looking at, you need to fix that notion of aggregated data to define more precisely what you mean.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yeah.

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

Because that could mean data pooled across lots of patients or it could mean data that has been aggregated on a particular patient across different sources, one of those...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yeah.

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

Is going to be a lot harder to do than the other.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yeah, Leslie actually...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Raised the exact same question when we were talking about this yesterday and I think David it's the later, it's for a single patient what has been aggregated on that one patient that you could return to them that's the discrete thing we were looking at here that's not to say that the other thing about aggregated data, you know, as a whole is also not important to return back in terms of like summaries of research that has been conducted on PMI data and things like that.

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

Right, right, so...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

But for this number seven we were thinking of the later.

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

So, you know, I would just suggest clarifying that language before you show this slide...

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Yes.

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

To lots of other people that's number one.

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

Sure.

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

And number two is the downside of the ability to do that means that you have to track the identity of the data very carefully through the whole process and that's going to expose more privacy issues. So, you know, the reverse ability of the anonymization that's going to be necessary to expose the data to the researchers is, you know, a risky step, you're going to have to do it but just be aware of the risks. If you're going to make it so that the consumer can get their data back out you're going to have to maintain ties to that data which would put you at risk of exposing identity to other people who could reverse engineer it so...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Or recommendations that we follow the actual identity service being separate and distinct from the actual storage of the data itself how could we use best practices, encryption at REST, what would we recommend there, I think that's coming out of a Privacy and Security Workgroup but your point is well taken, we have to make sure that if this is the eventual vision, which it is, that the design principles incorporate all of these things both technically and from a consent point-of-view.

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

And you...and so where I was headed with that is you could imagine treating data donors differently than patients whose data was swept up through an HPO and you may wish to do that for other reasons, mostly political, but if you're a patient donor you will have had to identify yourself, provide proper consent, which will have to be memorialized somewhere and then go fetch your data and contribute it. You could have an independent system maintain the mapping of the contributed data to the donors and identity, you know, a safe, what do they call it...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

A safe harbor, but, you know, what I'm trying to say...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yeah.

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

A third-party firewalled off entity because that's a flow that makes sense. And then that third-party entity could take your data when you log into the website and then turn around and query using the opaque identifier into the research cohort to pull your data out.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

That would be much harder to do with data that's captured through the HPO process and I suspect that some of the data proprietary concerns about researchers who have worked hard to capture that data will make this a little bit less clear whether they even want it to happen, you know, this is a data parasite problem that has been heatedly debated in the medical press over the last couple of months and Obama mentioned it in his press conference saying...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

You know there were proprietary concerns on some of this data that make some of these issues tricky. But if it's your own donated data there is no concern.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right and when...

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

You may want to carve them out.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And is that true, is it that there should be a common design approach regardless of whether it's voluntary and coming from the HPO with regard to where the entity information is stored versus the actual information itself and then but there are different levels of permissions associated because of potential proprietary nature. Because, do we really want to have that situation where there is a distinct difference between the data and data assumptions coming in.

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

Yeah, I mean that gets to the data parasite question you know...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

And the data provenance...

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

Because any...

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Of course you want to know...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Correct.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

The data provenance in general you do.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

Yeah, I mean, I...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And that should be carried forward from whether that's being swept from the HPO or being swept by the individual itself.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

You've got consent information, you have provenance information, you have data identity information and there are some assumptions that have to go forward in order to make this data available independent of which type of input that was. So, have there been discussions about this Maya that have recommendations that we could see or is that still in development?

Maya Uppaluru, JD – Policy Advisor for Health Data Analyst – White House Office of Science & Technology Policy; Division of Science & Innovation – Office of the National Coordinator for Health Information Technology, Department of Health & Human Services

So, there are probably some high-level recommendations on this topic in the Advisory Committee Report. One thing I can do in terms of...maybe for the future, the next meeting, I can kind of excerpt that for you guys and locate where it might be in the report and see what was said about it previously, but I have a feeling that all of these issues are to be determined.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So, I really think it's important to go back to the transcripts or read those comments about...that David and Dixie just made because if there are recommendations that we want to put forward that are just principles about good data security management, as the two of them just outlined and I think we heard echoed in a NIST presentation to us at the Standards Committee, perhaps last year, about the importance of segregating these types of data, that might be a recommendation that would come forward from this group even if it may or may not be within our purview important enough to articulate and emphasize.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

This is Dixie, I don't see any need to segregate it, and maybe I don't understand what you mean, but you certainly need the metadata to indicate what, you know, what the data provenance is for various data. But you know...

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

Well, Dixie, this is David, the concern, segregation may be the wrong word but if you donated your data and the data wouldn't be there without your donation effort then having a clear path to see what they've done with your own data and retrieve it back, if you would, is I think hardly controversial but if your data was swept up by an HPO from a research process it's not so clear that the researchers who did the work to organize and capture the data and perhaps supplement it with their own labor are willing to see that go back to the consumer number one.

Number two, you might not know how to match the consumer to the data in the cohort, hopefully we've solved that problem, and I just think that's a hot topic that's not resolved in the court of public opinion.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Sure in the court of public...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And in a court of law.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

I mean you're talking about...

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

Yeah, yeah not to mention the law.

Claudia Williams, MS – Senior Health & Health IT Advisor – Office of Science & Technology Policy – White House

This is Claudia, one principle of course of this particular cohort is that people...they'll be a different form of engagement and ongoing back and forth between the participant and the cohort regardless of where they came from. So, if you go back to the ACD report this concept of having a portal or other place where you...we might be able to share back information about the studies you were in, your actual results, your own results is a core principle that's been part of this the whole time.

Obviously, decisions about exactly what that looks like, exactly what information, at what point have not been resolved, but I would say that the cohort is moving forward very strongly in the direction of returning information to all participants and trying to structure things to enable that to happen and it won't matter whether they're from the HPO or whether they're donating their data that will apply across the whole cohort.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

That's good to hear.

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

Claudia, this is David, one of the things about that which has confused me from the beginning is that many places in the report it sounds like the intent is to leverage data that has already been captured, hence some of the HPOs that already have massive, well relatively speaking, massive genotype, phenotype databases would be recruited into the cohort, but you're implying something that's completely fresh and start from scratch. Could you clarify that distinction?

Claudia Williams, MS – Senior Health & Health IT Advisor – Office of Science & Technology Policy – White House

No, yeah, sure, I mean, and again all of this will be determined, but just based on, so the idea would be even if I'm a person coming from an HPO I'm still consenting to be part of this study and as part of the consenting I'm consenting that information that my provider has already collected will be sent into the data coordinating center and also consenting to baseline exams and data collection of other sorts. So, it's not going to be a mystery to me, I am actually consenting to be part of this and only once when I have consented will my data flow into the coordinating center.

So, it's unlike previous efforts that have strong large scaled data analysis on free clumps of data without consent because it falls into various HIPAA waivers and other things. Does that make sense?

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

Yeah, that does, that puts a big burden on the HPOs to go re-contact every one of those patients in those big databases to re-consent essentially, which that makes a lot of sense so that's just a big burden.

Claudia Williams, MS – Senior Health & Health IT Advisor – Office of Science & Technology Policy – White House

Yeah that...I mean, the principle that this project operates under is it would not be in line with the kind of transparency we want and the kind of engagement we want to simply rely on data that's already been collected without a re-consenting process. So, that has been...

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

Good.

Claudia Williams, MS – Senior Health & Health IT Advisor – Office of Science & Technology Policy – White House

That is the assumption we're working under.

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

Thanks, that helps...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

That's good.

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

I appreciate that.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So, I'm mindful of the time and we had a lot of good dialogue, a lot of good I think reframing how we want to present our work, great discussion. So, I'm mindful of public comment and Michelle I think we need to do that.

Public Comment

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

Thanks, Leslie, Lonnie can you please open the lines?

Lonnie Moore – Meetings Coordinator – Altarum Institute

Yes, 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

We did have a few comments in the public chat, I'm not going to read them though but I will share them with the group following today's call.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Great any others Lonnie?

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

It looks like there is no further public comment.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

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

So, thank you all and our next meeting is on April 13th. So, thank you Leslie for leading us through today's call. Leslie won't be able to join us on the next one so we'll have Andy lead that one.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yeah, thank you, guys and there's lots of rich information you've given and so really appreciate the thoughtfulness. So, have a great day.

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

Thanks, Leslie.

Gil Alterovitz, PhD – Faculty, Center for Biomedical Informatics – Harvard Medical School; SMART/FHIR Genomics Lead

Bye.

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

Thank you, everyone.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Thanks, bye.

Steven Keating – Patient Advocate/Consumer – Doctoral Candidate, Mechanical Engineering, MIT Media Labs

Thank you.

Public Comment Received During the Meeting

1. Ty Faulkner: Ty Faulkner - Rural & Urban Health IT - comments ... to support education, awareness, consent recognized collection of underserved and minority patients genome data including nursing home patients data, how groups like ours support your work as "trusted" community based engagement organizations?
2. Ty Faulkner: I really like the members comment just given on providing clarity of permitted use and disclosure of PHI. Although I was clear and could here all of the various statues or sources of discloser regs that he referenced... I heard HIPAA and it wasn't clear but did he say "CLIA" and something else? Would be nice receive more information on the disclosure reg sources he referenced?
3. R Boyles: I would like to make the group aware of the NIH funded project PhenX which has consensus measures for research and includes common measures in areas like demographics.
<https://www.phenxtoolkit.org/>