



Health IT Standards Committee

Precision Medicine Task Force

Final Transcript

May 11, 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. Andy Wiesenthal?

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Here.

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

Hey, Andy. Leslie Kelly-Hall?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Here.

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

Hey, Leslie. Andrey Ostrovsky?

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

Here.

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

Hi, Andrey. Betsy Humphreys?

Betsy Humphreys, MLS – Deputy Director – National Library of Medicine

Here.

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

Hi, Betsy. Christina Heide...Marissa is in for Christine I believe.

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

Yes, that's right, hi.

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

Hi, thank you. David McCallie?

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

Here.

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

Hi, David. Dixie Baker?

Dixie 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.

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

Hello.

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

Eric Rose?

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

Here.

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

Hey, Eric. Gil Alterovitz?

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

Here.

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

Hi, Gil.

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

Hello.

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

Jim Breeling? Jon White? Joyce?

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

Here; I'm here.

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

Hi, Joyce.

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

Hi.

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

Ketan? Mary Barton? Matthew Might? Mitra Rocca? Stan Crosley? Steven Keating?

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

Hi, here.

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

Hi, Steven. Terry Rauch? And from ONC we have Jamie Skipper and Jeremy Maxwell; is there anyone else from ONC on the line?

Debbie Bucci – Office of Standards and Interoperability – Office of the National Coordinator for Health Information Technology

Debbie Bucci.

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

Hi, Debbie; I'm sorry. And with that, I will turn it over to you Leslie and Andy.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Hey.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Hey.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

We're all set, right?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes, go ahead Andy, you start with comments.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

I should start. Well I think we're just here to continue the work that we have begun, which is to continue to discuss the recommendations that we are going to be formulating on interoperability and other aspects of the work, and perhaps also some of our parking lot items. So Leslie, I don't have much other than that to say; this is a continuing discussion so that we can bring some more final product to the Joint Committee Meeting next week.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yup, and I'd like to just focus our time on discussion so we'll get going. We did ask for...if there were any updates that were relevant to our work and received information that yes, the Patient-Centered Outcomes Research Organization has some new information that they were working on that is very relevant. So with that, I'm going to turn it over to...oh, I guess we still need to go through the basic slides, right? So next slide... Here are our great members.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Here we all are.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

There we are. Next slide. This is just a reminder of our tasks in the Precision Medicine Initiative of accelerate, adopt, and advance. Next.

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

And charge.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Is the task force charge that we've been working on to date; and we'll move on to the next; and our work plan. So this is our finalizing our recommendations and then May 17, next week Andy and I will be at the Joint Committee and presenting those findings. Next. We've all seen these before. Okay. So we've talked about this, I think...Andy, do you have anything to add to these? This is what we've already reviewed in our last meeting.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Yeah, no I don't. I think we're fine.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay. All right, next. Next slide, please. So are we PCOR is first and then we go to discussion, correct? And we're going to start with slide 14 in our discussion, I believe. So shall we just go forward with PCORI? Michelle?

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

Jamie?

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

I think so, yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yup.

Jamie Skipper, PhD, BSN/RN – Senior ONC Scientist, Coordinator, Patient Centered Outcomes Research – Office of the National Coordinator for Health Information Technology

Absolutely, I can go ahead and get started.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Super, thank you very much. Welcome.

Jamie Skipper, PhD, BSN/RN – Senior ONC Scientist, Coordinator, Patient Centered Outcomes Research – Office of the National Coordinator for Health Information Technology

Well thank you and thank you for the whole entire task force for inviting us to...inviting us to come and tell you about the great work that we're doing around PCOR. So we're on slide 1 of my slides, I see that the numbers are a little different, so I'm just going to say next slide, if that's okay. Oh, I see, you do have the right numbers. Okay, great.

So, first of all thank you and I wanted to...it's exciting for us to come and tell you what we're doing, especially as you're finalizing your recommendations for, among many things, the data infrastructure requirements for precision medicine. We want you to be aware of concurrent data infrastructure under the auspice of patient centered outcome research that we believe would hopefully, and we believe are important and can be leveraged for precision medicine. So I'm Jamie Skipper, I'm a Senior Scientist here at ONC and am ONC's Coordinator for our Patient Centered Outcome Research effort. So you can go to the next slide, which is slide 2, which I think you're already on.

So I'm going to assume that most of you are aware of PCORI, which is the Patient Centered Outcome Research Institute, but I want to provide a little bit more background before I go into our projects. About the relational structure between PCORI and HHS and the PCOR Trust Fund and how all of the PCOR activities are tied together and I'll only spend a quick minute on that. And then I'll give you a short overview of the PCOR projects...have going on at ONC. I don't want to take too much time because I want to have enough time for questions, which is the most important part as you are finalizing your recommendations.

So with that, we can go to slide 3, which is the first background slide. In 2010 in the Affordable Care Act, the Affordable Care Act set up the PCOR Trust Fund in that legislation and so, as I said before, all of you, many of you are very, very familiar with PCORI, which is the Patient Centered Outcome Research Institute, which about 80% of the trust fund goes directly to PCORI to set up and conduct patient centered outcome research.

What a lot of people don't know is that about 20% of the fund also comes back to HHS where 16% of the total trust fund goes to AHRQ to conduct research on how to best disseminate PCOR research and how to best train researchers to do PCOR. And another...the remaining 4% goes back to the Office of the Secretary to build PCOR data infrastructure, and that portion is managed by the Assistant Secretary for Planning and Evaluation. That 4% signifies the piece around which ONC comes into play here.

So, you can go ahead to the next slide, slide 4; and that kind of repeats what I just said. So you have this 4% and what ASPE has done is they've reached out to...ASPE, Assistant Secretary for Planning and Evaluation, has reached out to the various agencies across HHS to partner with them to conduct various projects to build data infrastructure for PCOR. Of those many projects, ONC has five of them; so I'm going to present out five PCOR projects here at ONC, but just know that there are also other data infrastructure projects at other HHS agencies as well, that might also be relevant.

And so the vision at least at the ONC realm is to make sure that as we build this data infrastructure for PCOR, that we don't want to have a siloed data infrastructure but really that we're building this data infrastructure built on what we've...leveraging as much as we've...as much as we can on data infrastructure we've already been building for healthcare delivery and see where it can be extended for research as well as not just PCOR, when we're talking about research, but other types of research as well. And so that's why this is very relevant for the Precision Medicine Initiative.

So, next slide. We have five PCOR projects at ONC; Structured Data Capture, Data Access Framework, Patient Matching, Aggregating and Linking, Patient Generated Health Data, and Privacy and Security...the Privacy and Security Project looking at the landscape and blueprint for privacy and security. So next slide.

So the next five slides I'm going to be talking...I'm going to give you a quick overview of what each of the projects are about. So the first project, on slide 6, is Structured Data Capture, SDC for short. And the goal of this project is to provide four standards that'll enable EHRs to capture and store structured data and to use the structured data within EHRs to supplement data collected for other purposes. And what this really means is in this project what we envisioned was to enable the EHR to be the tool to help conduct the research instead of having researchers need different data systems to collect data.

So we envision a world where we ca...where if a site signed up to conduct a study or be part of a study, then instead of having the EHR that they want to use be reconfigured for that one instance, we wanted the EHR to have the capacity to bring in case report forms from an outside library, into the EHR, display it, where possible to be able to fill...auto-populate that case report form with relevant data in the EHR into...directly into the eCRF, the clinical...the electronic clinical case report form. And then allow the provider to then continue to complete the form on the EHR itself and then from the EHR, send that completed case report form back to the PI's library or repository.

Right now that...this project started in 2013 and right now we are in the place where we are...we have two standards, one based on IHE and one a FHIR-based profile and we are in the phase where we're piloting these standards and we're going to hopefully have a balloted standard for the FHIR profiles and the IHE profiles this fall.

So then we...to the next project, which is DAF, Data Access Framework. So the object of this project is to enable providers and researchers to access their patients' clinical information using modular and

substitutable standards and profiles. And this project has three phases; Phase 1 and 2 have been complete. Phase 1 was geared toward allowing providers to be able to run queries on their own data within their own EHR and then Phase 2 was to be able to run a query, a single targeted...a query to a single targeted external organization.

So now that we've got Phase 2 and Phase 3, we're now going into Phase...sorry, now that we have Phase 1 and Phase 2, we're now going into Phase 3 which is to...which is focused on enabling researchers to access data from multiple organizations, so across a network. And so where we are with this is we're also, you know developing now in Phase 3 a FHIR-based profile that we're hoping to have an STU by this fall and we're going to be piloting these...the standard...we've already got a couple of pilots onboard now, and we're going to probably complete the pilots by March of 2017. So next slide, that's slide 8.

And before I jump into this, I'll say that both the Structured Data Capture Initiative and Data Access Framework projects, those started in 2013 and that's why they're so far right now, where we have the standards in place and we're getting to the point where we're balloting them and we're piloting them. These next three projects that we have were just launched in fall, and so they...those completed deliverables won't be available for a bit of time, but there will be some deliverables that can be used for PMI already this year, and I'll get to that in a few slides.

But, the Patient Matching project, the goal of this project is to identify attributes for patient matching across multiple data sets, identify algorithms to perform matches in these context and deliv...and develop privacy and security specifications that enable real-time matching, linking and aggregating of patients and with associated claims and clinical data.

So this is not a project where its one end-to-end solution for patient matching, aggregating and linking but rather we're looking at five different very important areas that are important to this issue. We're going to be looking at improving data quality, standardize attributes and improving algorithms for match rates. We're looking to create an open source visual tool for patient matching and aggregating.

We're looking to define the security layer necessary to protect open APIs and facilitate the aggregation of data from multiple data sources. We're looking to include clinical data research fra...research networks and their nodes as we pilot and test these components. And last, but not least we're also working with the NPPES to look at how provider directories can also be a really important component to this. So next slide.

So our next project, the Patient Generated Health Proje...Patient Generated Health Data Project is focused on developing a policy framework for the use of patient-generated health data in research and care delivery. And right now what they're planning, in terms of their scope is to develop a policy framework white paper that identifies best practices for the collection and use of PGHD and research and care delivery through 2024. And what they're planning to do is they're also planning to conduct pilots about, a little bit more than midway through to test the policy framework con...the concepts in the policy framework paper so that they can understand how it works and then they'll finalize their final best practices white paper.

Now we can go to slide 10. And so definitely last but not least, our Privacy and Security project, which I didn't put on the slides here, but we are calling that PSP for short, everything needs an acronym in the government. The goal of this project is to develop a framework and pilot standards that support an

individual's consent preferences for different research scenarios. So what we're doing here is we're working with stakeholders, having discussions with them, creating a legal analysis and ethics framework about all the different regulatory, both national and some state laws, public health policies, in terms of the context of exchanging data for research.

And we're also doing a landscape analysis to understand what consent technologies are already out there, what capabilities do they give us and what can be done and what needs to be done. And then we're going to look at then identifying and harmonizing standards for basic and granular choice that can then serve as a foundation for trust, for data privacy and research governance.

So quickly, this year we...in 2016 itself, on slide 11, we've highlighted the things that we're expected to finish this year itself. So as I said before, in Structure Data Capture we're going to have the...an IHE profile and a FHIR-based profile available and piloted...and being piloted. In Structured Da...in Data Access Framework we'll also have a FHIR-based profile by the end of this year and we'll be piloting that.

In Patient Matching, Aggregating and Linking we'll hopefully have an open source visual tool for patient matching and aggregating. In terms of the PGHD project, we'll have a draft poli...we'll have a draft of the policy framework white paper. And then in terms of Priv...our Privacy and Security, PSP project, we'll have finished our stakeholder discussions. We'll have finished our landscape analysis for what consent technologies exist and we'll...and most importantly, we'll have completed our development of our precision medicine use case.

So our las...my last slide here, before I end is to really reiterate the things that you'll all be considering now for precision medicine and how some of our projects may be able to be leveraged or come into play in...as you think about data infrastructure for PMI. And what that means specifically, we have here is, you know as you think about how we can leverage data from EHRs to support phenotyping and other different types of data that's really important from EHRs for PMI, we think that the work from the Structured Data Capture and Data Access Framework projects will be valuable to look at.

We know that as you look at matching patients across the cohort for PMI that the Patient Matching, Aggregating and Linking work will be very important, as well as what I don't have here, what's important is going to also be the work that we're doing around open APIs. We believe that as you're thinking about how to collect patient-generated health data for PMI, which is a really important piece for precision medicine, then as we look at the policies in terms of how PGHD can be gathered will be important to really look at the discussion, the framework that we're developing through PGHD.

And last but not least, to be able to really have good consent mechanisms for the PMI cohort and to understand what abilities are there and where we need to go, we really believe that the PSP project will give some insight to work that you need to do there for the PMI cohort. I'll stop there and, you know I have a couple of the PCOR leads on deck to help me answer any questions that you might have.

**Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP;
International Health Terminology Standards Development (SNOMED)**

Thank you very much, that's extremely well-organized and helpful presentation and I'm going to take advantage of the bully pulpit and ask a couple of general questions and then throw it open to my partner in crime, Leslie, before the...and I have the whole committee ask their questions. I don't remember you saying, but who did you actually involve in these projects? What stakeholder

communities helped to formulate the recommendations that you've crafted for the SDC and DAF and PMAL projects?

Jamie Skipper, PhD, BSN/RN – Senior ONC Scientist; Coordinator, Patient Centered Outcomes Research – Office of the National Coordinator for Health Information Technology

Well for SDC and DAF, we've worked through the S&I Framework, the Standards and Interoperability Framework; both of those were S&I Framework projects. And so the communities are...there's not one stakeholder, there are multiple stakeholders. And one of the really interesting things about all the three projects that you're asking about right now, both DAF, SDC and PMAL there's...we've been very open about who's part of those conversations and I can actually send the links to the task force, in terms of the Wiki so that you can see the full list of folks. But we're really talking about stake...a range of stakeholders, not just a targeted set of stakeholders.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

That's what I would have expected. I'm assuming that it included the EHR vendor community, it included delivery systems, it included patient and consumer representation and others. So am I right about those assumptions?

Jamie Skipper, PhD, BSN/RN – Senior ONC Scientist; Coordinator, Patient Centered Outcomes Research – Office of the National Coordinator for Health Information Technology

Absolutely.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Okay.

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

Well, this is David, I'm going to object when I get my turn, I just want to register that I'm not sure that the breadth of involvement was adequate and some of the feedback was not necessarily followed.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

We'll get to you, David. I often try to, as I said on one call where you weren't there, I try to channel your comments.

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

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

So, I was right on top of that one. And so Leslie, did you have any comments or questions before we give it to David?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Sure. I had a question about the Precision Medicine Initiative use case that you're working on; could you describe that a little bit more?

Jamie Skipper, PhD, BSN/RN – Senior ONC Scientist; Coordinator, Patient Centered Outcomes Research – Office of the National Coordinator for Health Information Technology

The precision medicine use case is...that I specifically called out was one under the PSP project, and we have Jeremy on the line so Jeremy, do you want to give a little detail on that?

Jeremy Maxwell, PhD – IT Security Specialist – Office of the National Coordinator for Health Information Technology

Sure, yes. So Helen Caton-Peters and Devi Mehta are working on a use case around...they're actually working on three different use cases around PMI, and so they're looking at policy implication from, you know when consent needs to be captured, how it can be shared, you know and they're looking at instances where, you know, patient privacy may be, you know need to be considered. For example, you know unintended compromise, you know from disclosing genetic data that may, for example reveal a condition about a family member or something like that.

So they're considering these different policy and ethical considerations and identifying what...and then where we're going to use that, the use cases they develop in our work that we're going to start in Phase 2 of our work for standards development and harmonization to implement some of the research consent they identified that's required.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Okay, thank you.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

You said there were three; so there's consent and how to share that and then there's standards that have been named, what's the third one?

Jeremy Maxwell, PhD – IT Security Specialist – Office of the National Coordinator for Health Information Technology

So no, there's three use cases related to consent in different scenarios.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay. Thank you.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Okay. All right, David, since you spoke up rapidly, why don't you have at it and ask your question or register your concern.

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

Sure, thanks. And I apologize for interrupting, I just wanted to connect the question about vendor support with this comment which is, mostly concerns around the SDC effort, which I think is under...it's over-engineered and under-delivering in terms of an approach that would be more powerful and easier for vendors to implement. In particular, the need for a new forms definition seems...an approach based on forms definition seems too constraining. We have a perfectly good forms definition language called HTML and we have a way to push HTML into EHR workflows with SMART Apps that's now supported by quite a few, all of the large vendors and quite a few others and non-EHR vendors as well. And then we

have, with FHIR the ability to move data in and out or across those boundaries as needed, contingent of course on having the right profiles in place to support the FHIR transactions, but you know that's a hard problem no matter which way you...which approach you take.

So I have, from the beginning of the SDC project raised concerns that it was too much driven by old notions of form definition languages and Josh Mandel and Stan Huff and I presented to the SDC workgroup a number of times, arguing for this broader approach with SMART Apps instead of SDC forms and we got some traction and I think the process improved somewhat. But I'm not at all convinced that there's broad EHR vendor support for SDC, because I think it's a too narrow way to solve the problem. I think you can accomplish everything SDC wants with a broader set of capabilities that we're already building in. It, you know, I have not engaged with the group recently so I may have missed recent, you know changes and I apologize if I'm just out of date.

On the DAF work, I think the thoughts there are good, but where the action is happening is in the Argonaut Project, as far as I can tell in terms of at least the DAF or getting agreement on profiles for vendor-exposed APIs that would be required for the 2015 edition certification, which is of course what the vendors are going to drive to, because that's, you know the definition of staying in business is you have to meet the certification standards. So the Argonaut group is pretty actively and aggressively nailing those profiles out one-by-one and I would urge attention to that, because that's, you know that's lots of vendors and lots of work.

I get concerned about the DAF notion in their Stage 3 that they're going to...what looked to me like define a new query language based on FHIR, which just seems like totally counterproductive compared to using FHIR as the export format and then letting the vendors of the various databases that are being accessed to use their own internal query languages to pull the data that needs to be exported. You know, ONC has tried a number of times to reinvent SQL and every time they try, they surprisingly don't get there and I don't think we should try that again.

The other two, I don't know very much about. It makes sense to have policies around patient-generated data and the privacy and security issues, as long as their done with, you know attention to practical implementation constraints. But I don't have much to offer on those. So mainly just raise the concern about SDC and suggest that the DAF meat on the bones is in the Argonaut project world at the moment.

**Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP;
International Health Terminology Standards Development (SNOMED)**

Thank you. Any reactions?

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

This is Joyce Sensmeier; yes, I just want to thank Jamie for her presentation. I think it was excellent to see that delineated and informative to this group. Two points, or really one point that relates to the SDC that I would like to make is there are pilots going on, as she mentioned, and those are at Duke University and University of California San Francisco. That work is still under way so I think it's important to know that there will be learnings coming out of that that will inform this work.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

When did...Joyce, since you seem to be well-informed, when do those exp...those pilots anticipate concluding and producing information for public consumption?

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

That is a great question; I would put that back to Jamie. I did discuss this with Steve Posnack yesterday, but he didn't talk about the end result.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Okay.

Jamie Skipper, PhD, BSN/RN – Senior ONC Scientist; Coordinator, Patient Centered Outcomes Research – Office of the National Coordinator for Health Information Technology

So the SDC pilots are aimed to completely conclude by the latest March, 2017. To answer some of the previous questions; I agree that the original SDC profiles that were IHE-based were very form heavy but the FHIR profile for SDC that they're testing now is FHIR-based and so that might address some of your concerns.

In terms of DAF, completely agree that we need to work with what's coming out of Argonaut and want to just also share that the latest DAD STU that's going to be balloted this fall takes into consideration a lot of feedback that we got in collaborations that we're having, both from feedback from the Phase 3 pilots as well as feedback from what the Argonaut teams are doing. And so that'll be reflected in the fall STU for DAF.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Okay.

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

Umm...

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Go ahead.

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

Hello?

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Yes, go ahead.

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

Oh yeah, this is Gil Alterovitz; I just had a question or actually first, yeah I wanted to echo actually some of the...a couple of the comments that David McCallie said. I'm actually calling from Montreal where we're having the HL7 meeting right now and we're going to actually try out, there's going to be a clinician Connect-A-Thon; we're going to try out some of the SDC things and so we may have some feedback. We're going to try and focus more on patient survey items when we're using that, so that may be rather limited feedback, but if we have that, we'll...we can make sure to reach out.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Great, thank you Gil. Any other questions or comments?

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

This is Eric; just was wondering, David, can you repeat the acronym that you were referring to as the alternative to Structured Data Capture, it ended in ML, but I didn't catch it all.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

HTML.

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

You're talk...

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

HTML. Yeah, so let me explain what I meant by that because it's a little cryptic and I apologize for that. The, you know the counter-approach...well first off, SDC will work, it can be made to work, there's nothing wrong with SDC in and of itself. My concern is that it's overly limiting and will require the vendors to do additional work that they don't need to do because there's a more powerful alternative already available, which is a SMART App.

So with a SMART App, I can push anything into the clinicians workflow that you can define with HTML; that could be a simple form, if that's all I needed, but it could be something as complex as some visual tracking, you know challenge that I want the patient to do, or it could be a graphical display and I want you to touch the screen where something...where some threshold is met. In other words, you could be much more powerful with existing engineering commitments to do SMART Apps than you can by limiting to a lightweight, and it is a very lightweight forms definition language that SDC is adopting.

So it's extra work for less power, and that's why it rubs some of us in the vendor community, the wrong way. The FHIR part is fine, that's not up for debate, it's really this notion of a lightweight forms definition language. Why would you constrain yourself to that when you can push a web...you have to push it, even SDC requires a web browser to be pushed into the conversation. But it's going to require a new authorization, authentication process; we've already figured that out with OAuth and the SMART Apps. It's just reinventing a wheel that has less power than one we've already got.

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

Okay, so the alternative would be using SMART Apps...

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

Smart...yes.

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

...which are part of the SMART/FHIR approach, right?

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

Yeah, yeah...

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

I just want to make sure I've got this straight.

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

...could add whatever, you know conversation you need to capture data as a SMART App, and it could be as simple as a simple form or it could be as complex as something we haven't imagined yet.

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

Okay and has the appropriate semantic tagging so that things get stored in the way that it's...as possible.

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

Yeah, so the big open question, and I have not, I wish I had a thoughtful answer to give, the big open question is, let's say you have a whole bunch of data that you want to aggregate together as, you know a chunk of data related to some questionnaire. How do you store that questionnaire data in the EHR?

And at the moment they're using FHIR questionnaire as the data model; no vendor has implemented that, as far as I know it's on anybody's radar, and the big question you get from that is, so it's in the EHR as a FHIR questionnaire, what can the EHR do with it? And at the moment, the answer is nothing; they're just storing a blob of JSON-structured data. And maybe that's useful, I'm not sure and I don't know that's a harder question. But I think the que...the issue about the visual presentation and the use of yet another new forms language, even if it's very lightweight, just doesn't seem to be sufficient. I...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

This is Leslie; I'd like to comment on that, too because as we look towards the patients participating in this cohort, we want to make sure that we're using very visual and very configurable tools. So, HTML lends itself very well to doing things like WACG that allows us...which is an Internet-defined, you know web defined accessibility standard. Without that, we're not going to have the flexibility for people with differing levels of disabilities, be able to use and communicate back to the provider in a way that is good for them. And this population is going to be active in care largely, and so they might have different needs that if we constrain the way the information flows visually, as we have today, it becomes difficult for those with not full function to participate in the ecosystem.

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

I have a comment; this is Dixie.

**Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP;
International Health Terminology Standards Development (SNOMED)**

Go ahead, Dixie.

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

And they're piling up now. First of all, I want to respond to David. David, if you use HTML, you can present user language in the presentation, but still capture the language with metadata that would allow you to pull it back into the EHR; so that's, you know I don't see that as a barrier. But, to address...my real comments are addressed to Jamie and, as she knows by now, I'm very collaborative, so I wanted to let you know about a couple of things that directly relate to your projects.

One, the PMAL, the Global Alliance for Genomics and Health is just launching a working group that is addressing exactly that topic on an international basis and I would think that the two could be, you know could somehow at least communicate with one another.

The other two, the PGHD, the patient-generated health data; as you know, there are the PCORI includes a category of research group called the Patient-Powered Research Network and all of those, Patient-Powered Research Networks including the Genetic Alliance one that I work with myself, all of those have been using patient-generated data in research for years. And then...and I'm sure that...so I would encourage you to use those groups as...get them involved in that project.

The last one, two comments and the one, ONC just did a landscape of, you know technologies for automated consent, but I guess this one is focusing on research. And I would like you to be sure you know that the Genetic Alliance has a Platform for Engaging Everyone Responsibly they call PEER System that has implemented granular, dynamic, automated consent and is deployed now in over 40 different advocacy groups and other research sites. So, I'd be happy to tell you about that, but there are...there's work being done in all three of those areas that you can capitalize on.

Jamie Skipper, PhD, BSN/RN – Senior ONC Scientist; Coordinator, Patient Centered Outcomes Research – Office of the National Coordinator for Health Information Technology

Well thank you Dixie.

Jeremy Maxwell, PhD – IT Security Specialist – Office of the National Coordinator for Health Information Technology

Hey Dixie, this is Jeremy. Specifically on the privacy and security piece, thank you for your comments. We do have the same contractor working on...who worked on the previous landscape analysis is working on this landscape analysis, so we're making sure that we're focusing on different questions, different scope and different audiences with this one. And then we actually talked to Stephanie from Genetic Alliance yesterday actually, so we have been in contact with them.

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

Oh. Excellent, excellent, I'm glad. Good, thank out.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

So we've heard from a number of committee members; other comments?

Jamie Skipper, PhD, BSN/RN – Senior ONC Scientist; Coordinator, Patient Centered Outcomes Research – Office of the National Coordinator for Health Information Technology

I...

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

This is...oh sorry, go ahead.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

No, you go ahead.

Jamie Skipper, PhD, BSN/RN – Senior ONC Scientist; Coordinator, Patient Centered Outcomes Research – Office of the National Coordinator for Health Information Technology

Again this is Jamie, I just wanted to let Dixie know, thank you for your comments and we are actually working with the PPRN folks and with PCORI with PGHD. And in terms of PMAL, Debbie, you're on the line, right? Do we...have we already talked with Global Alliance?

Debbie Bucci – Office of Standards and Interoperability – Office of the National Coordinator for Health Information Technology

Yes I am on the line and not yet.

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

Yeah, that's a brand new workgroup that you may not even know...they're just launching it; in fact, we haven't had even the first call; they're currently scheduling it. But, you know, that's a good thing because the timing may be very good.

Debbie Bucci – Office of Standards and Interoperability – Office of the National Coordinator for Health Information Technology

I know there are a number of workgroups that we have been asked to present at, but I just, as you say, there are many of them are just ramping up.

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

Mm-hmm.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Okay. Someone had a comment.

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

A quick question here from Andrey Ostrovsky and this pertains to the discussion around PCOR. One observation I've had is that the engagement of patients or consumers in research or focusing research on them largely stems through medical settings and I think there is a huge opportunity to engage consumers, not just patients in more community-based settings.

And I've mentioned it before, I just want to bring it up again that there may be some really neat opportunities to inform the Precision Medicine Initiative if there were either...if there was education or capacity-building to engage community-based providers in some of this really interesting work, because these are traditionally folks not in any way associated with academic medical centers and with no research capacity whatsoever. Most of them don't even know that there is a Precision Medicine Initiative going on. So, I think if that ever becomes of interest or a priority, I'm happy to serve as a conduit to connect to those leaders. Just wanted to put that out there.

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

Hey, may I respond to that? This is Dixie; even though the PPRNs are called Patient-Powered Research Networks, those have, the PPRNs have no connection with medical institutions, they are all community-based, just exactly like you're describing.

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

Oh, I guess...could you give me an example of what type of community-based organization because I'm literally present...

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

There are 20 of them, 23 of them now and I...one of them is the Community Empowered Network for All, CENA and that's the one that Genetic Alliance has. But there's an autism one, there's a...

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

Okay.

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

...sexual orientation one.

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

I see.

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

They're generally condition-specific...

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

Yeah, that sounds right.

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

...the Patient Powered Research Networks, you'll see the list.

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

Got it. Okay, great, I'll look into that. I think the types of providers I'm referring to are less so advocacy groups and kind of self-aggregated patient or consumer groups and more so the providers that serve those populations in the community, largely Medicaid funded.

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

Yeah.

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

And I think there may be an interesting opportunity there, because that's perhaps a subset that isn't engaged that could be; particularly with respect to populations with low socioeconomic status and that are more subject to health disparities and, you know...representative sampling in access and things like that. Thanks, thanks for clarifying that though.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Thank you. All right, so additional...

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

So Andy, this is...

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

...questions? Eric, is that you?

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

...Eric Rose; I had one quick question for the members of the task force. So one of the things that stood out here, and I just want to make sure my understanding is correct, is that of course with PCOR there's a need for a use case where a user in the EHR or the clinical information system is presented with a data entry form because there are specific pieces of data that must be captured for the study to be able to be done. My understanding of the approach of the Precision Medicine Initiative is that it would be...it would cull the data that's already in these systems, but wouldn't necessarily involve a use case of defining specific data elements that end users would be prompted to enter, that otherwise wouldn't be getting entered in the clinical information system.

And I just wanted to see if I'm correct that that's not really a requirement because if it is, then we do have to really think about what we want to recommend for that workflow. If not, then it's a non-issue.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

So Eric, I'm with you. I think for the primary purposes of the Precision Medicine Initiative, my understanding is the same as yours, that that is not required. For people who are interested in doing additional research with that database, it may be necessary, but that's a research workflow, that's not, you know and maybe I'm splitting hairs, but it's not really part of PMI. It is something that researchers will be doing all of the time; so the broader use case would subserve that need, take care of that requirement.

And I think that's what, you know what I heard Jamie saying is that they're designing this not for the PMI, they're designing these things for these very broad use cases and PMI may be served by them, and they're just trying to help us understand how that fits. So, it seems to me we're still on the right track, they're on their track and there may be things that they're doing that would aid the Precision Medicine Initiative. Jamie, do I have that right? Did I understand what you said correctly?

Jamie Skipper, PhD, BSN/RN – Senior ONC Scientist; Coordinator, Patient Centered Outcomes Research – Office of the National Coordinator for Health Information Technology

Yeah, I couldn't have said it better.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So would there be a specific recommendation that we'd want to put forward with regard to that, Andy?

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

We...well, you mean limiting or just making sure we've got it straight, I'm not sure.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

I don't know that we need to, you know, it seems to me that, you know that PCOR is doing what they're doing and they're trying to be helpful and saying, all right, here's what we're doing and here are the parts of it that we think will help, but we're doing what we're doing. And we're saying, we have a set of recommendations and they relate specifically to the Precision Medicine Initiative.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I...okay.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

And it's whatever...of whatever others are producing as far as we, you know we would expect researchers using the database that is created of genotype and phenotype; we would expect those researchers to use tools that have been developed for researchers and this set of tools will be among them.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

All right, so...

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

By the way, I'm surprised, you know, some of the vendors are already and I think David was kind of articulating this, some of the vendors are already developing research toolkits that allow triggers to stimulate the return of a form to the clinician of record to amplify on data that is needed for the research project, but hasn't been recorded in the electronic health record to that point.

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

Yeah...

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Same thing, by the way is useful for public health as they do case investigation, there are things that are ordinarily collected by doctors and there may be additional questions related to the specific reportable condition that a physician needs to answer, that they didn't record during the initial encounter.

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

Exactly and I'm just saying that a SMART App and the appropriate authorization and FHIR services that make SMART Apps work is an adequate way to solve all of those problems, without requiring a new set of standards.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So we have said before that we had a bias for using existing standards and where standards were named in future certification efforts that we would try to basically get two-for-one, you know...

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Right.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

...so that if there was work in industry going forward, we had a bias for using them. So what David's articulated, I guess and others agree is that we have work already being done for certification purposes that has a good use in this, and that one of our recommendations therefore is that we more closely align this work that ONC...closely align this work so that we are not replicating, but more importantly, that we're actually able to implement faster because work is already there.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Yeah. I want to pause for a second, Michelle; can we do a time-check? This has been a good discussion and I want to be sure we're not going to shortchange other elements of our agenda today; because we only have...we have a time limit that we're rapidly approaching.

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

Yeah, I think that we might need to move on to our next topic. Thank you, Andy.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

All right; well, it's been a good discussion. I...Jamie thank you very much and to your team for being present; it's been very valuable to us and unfortunately, we need to move on in our agenda. So, we appreciate your help.

Jamie Skipper, PhD, BSN/RN – Senior ONC Scientist; Coordinator, Patient Centered Outcomes Research – Office of the National Coordinator for Health Information Technology

Thank you.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

All right, there is a next slide, I assume.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Its slide 14 is probably where...is where we left off last time.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Mm-hmm. There we go.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And, all of the items in the detail are things that we'd captured earlier for consideration of recommendation. So we talked about the role of the patient participating in this, using an individual App in the API model that when the health provider organization enrolls the patient, patients will act as an exchange mechanism for many providers and the data source for data not captured in the EHR.

That NIH direct enrollment should include strong assurance and identity proofing equal to the current patient portal's model and consider direct language and employ the highest Web, this is the WCAG standard I just spoke of earlier. And that in the API App model, patient connections to EHRs to exchange clinical or clinical information to NHS and designed with a reciprocal query in place. We talked a little bit about this earlier, but a strong theme from this group is, look the people who are participating should also have the right to retrieve, look at or use information.

And then we suggested that ONC to engage stakeholders and accelerate a process to determine the minimum data set if there was. We've heard from people that there could be for patient-generated health data to include vocabulary where gaps exist and use existing standards and efforts.

So the question is how does the group feel about these items? Are there changes, recommendations or gaps?

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

Leslie, remind me what the thinking was about the reciprocal query in place from EHR for patient-specific aggregate requests of PGHD.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So in some...

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

Who are you querying and under what authority and all that?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

We talked about if, and this is a question we actually asked the group last week in the...in our summary we met with the overall chairs of the PMI Initiative, it's the idea that if a health provider organization is registering a patient with the cohort, there is some information that's coming back to them. Is it that ID of that patient? Is it...which the NIH has said there will be a new record number. Does the provider have access to that so that they can use that for future queries? On query might be to get aggregate specific patient data, because it might be the first place they can go and retrieve data, especially the patient-generated health data and other information back in.

This initial say is it didn't suppose that the EHR or the provider had necessarily a role and future need of that information. But key information like a record locator or the patient ID up front, at registration could help the provider to integrate that in future care. And so did...the question was, what do we want to design or make a minimum that if a prov...health provider organization is registering a patient, do they have access to and is...in treatment, payment or operations, what is it that would be...we would need further guidance on? But is there information that should be exchanged back to the provider?

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

So I think...this is David again; I think the notion that identifier exchange such that the patient could be identified from the EHR into the research organization is an interesting and good idea. The notion of a...this is listed under API, it's...I mean maybe as a high level goal its okay but, you know who are you querying of these...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

...research organizations? That data could end up in dozens and dozens of different places and under what authority are you doing the query? And how do you validate that you're a provider that has a right to do that? I mean, it opens a huge can of problems to go solve, so, I mean I don't know, we just have to be cautious putting out you know, ideas that have absolutely nothing in place to be implemented. In other words, you know the patient can take their data from their provider and donate it.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

That's a simple, straightforward process. The HPO can donate, once they get consent, to the PMI but once that data's in the PMI, we don't really know what's going to happen to it, in terms of how the data's going to be apportioned amongst different research projects. I mean, I think a lot of that has yet to be worked out and probably will be pretty controversial. So going backwards, it's not clear to me who would serve it up.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Well, it would be...the discussion was around the NIH actual repository being the source of information for the purposes of this and not multiple sources downstream. However one recommendation early on, coming from the group or coming from the Policy Committee was patient's being made aware when their information is harvested and used. And there was further discussion on the value of this information has a huge lifespan, maybe even beyond the patient; is there opportunity and what degree of information should flow back to the health provider organization, if any, at the point of enrollment?

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

Yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And I think that this idea of reciprocity has been ongoing in all of our discussions, that how do we accommodate for a future learning health system when we are simply adding yet another end point and not a reciprocal relationship.

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

Yeah and, I mean it makes sense to me at a minimum to say to the NIH or to the PMI that if you're going to generate an ID that actually tracks this data, then it makes sense to consider sharing that ID back to the contributing system so they can match them together.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

They can create you know, an alias that says the NIH research identifier for this patient's data is X. Just be aware that that creates immense security issues in terms of potential compromise of the patient's data because if there's a tag being circulated in the external world that uniquely identifies the patient in a way that anybody with access to the EHR can find out, you've just now created a pretty easy way to identify all the research data...research subjects downstream. So...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So I think it's for consideration, right? Because the flip side of that is, as a...the flip side of that is, is it useful information in care or treatment and if so, then how is that found? We're just adding yet another element to the whole patient identification issue.

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

Yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So I think a recommendation would say, further work and consideration should be done on this rather than an absolute.

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

Yeah, I think it's a laudable thing to talk through, but it has a lot of consequences, not the least of which is that it's a research question and you have to ask, you know what clinical use should you be making of stuff that is hypothetical, you know, just the CLIA lab issue and other things.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

I mean, it may not be confirmed; it's a hypothesis, you don't know yet. Once it becomes scientific fact, then it can be circulated through...I don't know, it's an interesting question.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I think the group was more talking about just getting access to the ID allows them to then see...query the database for genetic information or for others related to that patient for care, not necessarily for the downstream research. One member of our group said the downstream research we need some notification for harvesting, there has to be something that tells a patient how often and why this is being used.

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

Yeah and just to jump in here quickly...Steven Keating here again; I think you're absolutely right in saying that and that we need to make sure patients and participants always have access to the raw data and not just results, we should view raw data separately from results because it can make a huge difference. And even just the ability for participants to see how many times their research has been accessed, so

their data has been accessed will provide incentive for them to contribute more. It's like we need to make sure that there's that kind of reciprocal relationship and so, you know for me, for example, whenever I write a paper, I can see how many times it was downloaded.

So, you know, yesterday actually on an e-mail I said my paper has been downloaded from 76 countries and that makes me want to publish more. And it would be the same with sharing medical data. So there's, even if the patient's not able to use the raw data, just them having access to it and being able to see how many people have used it could be really incentivized.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yup.

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

You know so this is David; I agree, but it's extremely complicated to pull that off just technically, much harder than keeping track of who's downloaded your papers.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

But fundamentally I think we're talking about the right of access in the same way that we are any other medical information for the patient and that that should be carried forward into this. Obviously there's much more work that needs to take place, but that that concept is quite important.

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

Agreed.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay. Are there anything else here, we'll go to the next slide? Umm, this is really about getting information from non-specific healthcare providers, other labs, PBMs, claims and so forth. We had this at a little bit longer time period; we have heard over and over again that meds are a high value content area, labs as well. The questions around patient identification and matching was brought up several times. Do we have specific recommendations that we want to make in this area at this time?

One of the comments we had earlier was that because of the Precision Medicine Initiative brings and entirely new set of data, do...how would claims data and payer data interact? Is there opportunity for misuse? There was a big discussion about if this should happen, how it should happen, are claims included? And I'm probably not paraphrasing it right trying to get bells ringing in people's head here about what we've talked about previously.

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

I mean I...

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

Question...Leslie?

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

Well this is Eric...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Dixie?

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

I'm not sure why the sources are limited to covered entities versus, you know like consumer technology and, you know all of these are still the healthcare system sources. Do we have another recommendation that reaches outside the healthcare system?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I don't think so; I think we should include that here. I think we've talked about it but have not put it on the slides; I think that's a very important portion to add.

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

Yeah, I think so, too because these don't, I mean they're, you know it's all still HIPAA constrained, you know and so they're more questions relating to, you know data integrity in particular and provenance and other things, when we start looking outside the healthcare system. But, the data are really important.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

In some ways...

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

This is Eric, I think these are high value sources of information and that it is worth emphasizing that an effort should be made to include them in the inbound stream for the PMI, but there's, I forget where it was published, but there was a paper published in the last few weeks that showed that EHR data, which we've often a lot of us think of as sort of the gold standard for what's going on with the patient or had huge gaps with regard to what medications patients were on that were discovered by collating claims data, which you know, we're used to thinking of as inherently flawed and crude and in many cases misleading.

So I think that definitely for meds having information from electronic prescribing networks, or in the case of the United States, electronic prescribing network, because there is only one and it has a monopoly, but it has the data, would be very important.

And for clinical labs, you know there's many of...I think that it's worth going after that, I think that the connectivity may be limited for a lot of clinical laboratories, but as far as lab data and claims, one thing I learned recently is that payers may actually get more detailed information on...or more usable information on lab tests that are performed than EHR vendors themselves, in particular they may get LOINC codes associated with claims, which I was very surprised to learn, and this is from somewhat of a major, national payer who said yeah, that we just told the lab that they had to put LOINC codes in their claims because we needed it for our analytics. They still have a little bit more pull with the clinical labs than the providers do; evidently, because providers usually won't get...don't get LOINC codes from labs. So I think that these, there's gold in them there hills is what I'm saying, and yes we do.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay. Great. Other comments from this area?

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

Yeah, this is David; I mean, you know I think first off the PMI has to decide whether this data is of interest to them or not, I mean it certainly sounds like it ought to be of interest because of the arguments that Eric just made and others, but it's kind of not our purview to tell them that they should be interested in the data. They'll either understand that it's valuable for their research use or not, number one. So I don't mind us saying we think this is probably going to be useful to you, but it's kind of the scientist needs to determine whether they care about it or not.

And then number two, which is may be an irrelevant point I shouldn't have brought it up, but number two just to caution the privacy implications here are astounding.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

Right, and if the patient when they access their portal and download their clinical data, they kind of know what that means, but if you are...if by so doing they are also giving carte blanche to go get every single thing about them from their payer and from the PBMs and from their pharmacist, that's gigantic increase in the exposure risk for you know, their data. And it's not the EHRs responsibility to warn them about that, but the precision medicine enrollment process had better make it really clear that if they carry through on this, you're essentially opening up everything about your clinical history to be fair game to be go and gobbled up for the PMI.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm.

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

That's a big deal, some people will want to do it, some people won't.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Very explicit education around that, if that in fact is taking place; in the end I think that you bring up a good point is that we don't know yet what all data will be relevant as we go forward and the data becomes available electronically. So we want to encourage that whatever consent framework is in place, it, as they mentioned earlier in the PCOR project that it often rechecked as new information is used or new harvesting is done of the data, or new sources of data come in. So, it's back to not just the harvesting of information, but new data sources would also require potentially new consents. Okay.

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

You know, some of these will give them, they'll be getting multiple copies of the same data here, you know the claims, retail pharmacies, PDMs, they'll all be...PBMs, will all be reporting the same you know, the same prescription picked up and paid for and, right?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yeah.

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

Why do we need multiples, I mean to address, I mean sort of addresses David's question, why would we want three different sources for the same data?

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

I mean Dixie the problem is you don't really know which source is going to deliver it every time.

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

Yeah, but look at the other end, you've got to figure out, is this the same prescription three times, you know.

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

Yeah, no that...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So that does bring up a good point as to, we don't have yet a good, and I think we made recommendations in the Standards Committee a while back to have a workgroup considering duplication, provenance and just a way to know these things are duplicates.

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

Yeah, I mean and most every pop-health company has de-duping logic, I mean it's a fact of life, you have to do it. And unfortunately, sometimes you have to guess.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm, right.

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

But de-duping will certainly be required. I just am concerned that we're opening the door to...by making the suggestion, we just have to be cognizant of the privacy issues and make sure that the person who's engaging with the Precision Medicine Initiative understands what parts of their data are going to be sucked in and tracked by...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And used. Well let's move to the next slide because I think we touch on this a little bit on the privacy or and the...we had question about what are the privacy and security implications of returning individuals data, the clarification regarding policy that facilitates patient data access and return of results, the same sort of thing. Liabilities issues of working with genomic data with respect to the researchers, obligated to disclose back to the patient; I think that's ob...not really in our purview, but it's the whole idea of what's being sent back.

Options related to the types of patient data or data patients that would like to have access and receive, but should it be clarified in consent if the consent does or does not apply to copies of data? So someone's queried data, harvest that data, now using it in another purpose; what are the downstream

implications for that? Does there need to be further work where notification and consents related to ongoing and further use of the data for research?

So those are, I think we've hit on a lot of those already today that because there is this huge, vast amounts of data potentially coming into as well as being stored originally, what further obligations do we have, beyond the normal medical record, to keep that safeguarded and also make it available to patients and contributors? Do we have specific recommendations we'd like to make around these areas?

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

I think we've already talked about some of them.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yup, I do, too.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Yeah, I think so, too.

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

And I would add the need to de-duplicate to this list here, too.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay. Are there any gaps in, I know Dixie you've been involved in a lot of different associated committees, David's access to the EHR world, Eric to all of the semantics and interoperability; do you, any of you believe we've got some gaps in our recommendations? I know...I didn't see one in these slides we talked about earlier was that ONC actually provide a diagram, a document that shows how...where all the workflows are, where all the data is moving, what standards are being used and the timeline that the work will be initiated. Because we really don't have a sense of an inventory right now, it's such a fast-moving target and, great example is Dixie connected dots today. So, are there other recommendations beyond not just this theme, but larger than that?

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

Well, have we made recommendations around the need for granular and dynamic consent?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

We only mention it here, the consent needed to be able to be revisited over time and based on what information is harvested or coming...data sources, but I think we can add that as well.

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

Yeah, there's...I don't think we need to specify the granularity or anything but there's been quite a bit of work around what, you know consumers typically want to...or they typically and often they want to specify, for example that the kind of condition that they're, you know that the foc...that the research will focus on. Like some of them will say, okay, I'll make data available for BRCA research, you know...and an institution. You know there are certain things that they typically, internationally even, they typically want to specify at a more granular level than all or nothing, anybody and everybody. So I think that mention it more granular than all or nothing kind of thing.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

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

I just, and it's David here; I mean agree in an ideal world, but the practical implication of that or the way research gets done with amassing and merging databases, keeping track of that level of granularity and trying to factor it in with real-time queries, where you're doing...

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

(Indiscernible)

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

...aggregations and stuff is just insanely difficult and I just can't imagine that they would take it on.

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

It's the, you know we're taking it on at the international level so I think we can probably handle it at the national level, too.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I'm constantly struck by, I can't remember who made the comment in our workgroup that this data has value not just through the patient life, but that data has value for a very long period of time, and in fact might increase in value as research is done against it and I think that has a different level...burden of responsibility for consent.

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

I think it's really important and I can even send you some of these data that, you know there have been studies that show that when patients are given some level of granular consent more than all or nothing, they're much more likely to make their data available for research than if they're just...it's just all or nothing. So there is you know we do have data that show that and it is definitely the...well it's definitely the Global Alliances' approach.

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

But how do you...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And Dixie, have they done anything in their suggestions about the use of data past the lifetime of the patient?

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

Uh yeah, I think the policy and the ethics framework both mention it, but I'll have to look it up. I can send it...I'll look it up for you.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay. Thanks Dixie. David, did you have another comment?

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

Well I'm just curious, I mean it makes total sense, but how do you do it? I mean is there a provenance standard that they suggest using that tracks...pardon?

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

The consent. Look at, actually the Global Alliance for Genomics and Health developed a list of here are the specific consent areas, and they're now working with the HL7 consent group to actually have that integrated into the HL7. Now I can send you guys a link to a paper that talks about this as well. So I'll send both of that to you. And you can do it through metadata, you can...you know, there are multiple ways you can do it.

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

Yeah, but the concern is, no...it's never been done, that I'm aware of, certainly not on the EHR side and the HL7 work has all just been paper, it's never been implemented.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

You know there was a demonstration project...

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

Well...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

...that HL7 last year or excuse me, at HIMSS last year there was a demonstration project that showed computable consent, granular computable consent by topic area, by time and so forth using FHIR as the underlying technology. And it showed great promise in this area.

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

Yeah, pilots have been done...

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

We're not talking about EHRs doing this, you know...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

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

...we're talking about in the research environment doing it. You know, I agree with you David, we've had this conversation before, I do agree that there are some real safety risks when you start segmenting data within a treatment environment, but we're talking about, you know making data available to a research community and so it's much easier to do there than it is in the EHR.

**Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP;
International Health Terminology Standards Development (SNOMED)**

Let me just interject, Michelle, this is Andy. Unless I'm mistaken, we're about to run out of time? Am I correct? We may have some people dropping off in the next 10 minutes?

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

Yes.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yup.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

So we need to wrap this up if we can, are there other things Leslie and Michelle that we need to focus on in the next seven or eight minutes?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

No, this is the last slide. I think what we'll do is compile these...all of these notes and potential recommendations.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Mm-hmm.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

We're having a discussion next week, the Standards Committee we can send out what we've heard and ask the group to comment maybe by the end of the day, on Tuesday at the latest or Monday at the latest, that would be great, maybe you can ask staff to meet with me and Andy on Monday late afternoon on the phone if we could do that and...

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Well, you know, just to handle some logistics, I'm always on an airplane then, so that won't work.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay. Okay, well we will...any other recommendations people have if they can forward that to Michelle and me and Andy on e-mail or the group that would be wonderful. Michelle, you want to do public...

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Great. All right, so we open up for public comment.

Public Comment:

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

Lonnie, can you please open the lines?

Lonnie Moore – Virtual Meetings Specialist – Altarum Institute

Sure. 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're already on the telephone and would like to make a public comment, please press *1 at this time.

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

It looks like we have no public comment. So we'll see how things go next week when Andy and Leslie present to the Committee. We do have a meeting on May 25, if needed and in June, and we'll let you all know if we need those meetings. So thank you all, we appreciate your feedback, as Leslie asked for and we'll be in touch. Have a great rest of your day.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thanks, Michelle.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Thanks everybody.

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

Bye.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Bye.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Bye, bye.