



**Health IT Standards Committee
Precision Medicine Task Force
Final Transcript
March 16, 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

Hi, Andy. Leslie Kelly Hall is not with us today. 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?

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

Here.

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

Hi, Christina. 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

Hey, Dixie. 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? Jim Breeling?

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

Here.

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

Hi, Jim. Jon White? Joyce Sensmeier?

Joyce Sensmeier, MS, RN-BC, CPHIMS, FHIMSS, FAAN – Vice President, Informatics – Healthcare 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.

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

Hey.

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

Ketan? Mary Barton? 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. And 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. And I don't think Maya has joined us yet. All right, with that I will turn it over to you, Andy.

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

Thank you very much and welcome to everybody. For those of you in the Washington, DC metro area, congratulations on making it somewhere you could actually join from. For those who aren't from the Washington, DC metro area, there was a minor catastrophe on the Metro two days ago causing the entire Metro system to be shut down from last midnight until tomorrow morning, so it's thrown a modest monkey wrench into peoples' transportation plans. So we will do our best to navigate that and we've had our roll call.

Today we're going to hear from one of the most innovative public programs that we are currently conducting in the United States. And so I won't steal Jim Breeling's thunder from the Department of Veterans Affairs; but that will be a really special presentation. I don't think I need to...we've had enough meetings so that I don't need to remind everyone of the ONC role in precision medicine or the charge for our task force and the roadmap of our meetings is there for everybody to view, so I won't review it.

What I'd like to do is move to the eighth slide in your pack, so if we can flip forward to that from the perspective of those folks who are viewing it online. And ask our presenters, and we forwarded this to

our presenters today so they've had a little advance warning, but, we think there are some questions we'd really like you to address in addition to the key points that you'd like to emphasize from your presentations.

So first and foremost, what is your agency's specific mandate and contribution to the Precision Medicine Initiative? Second, what types, data types are of the highest priority for your work that relates to PMI? What's the minimum data set you would require for PMI? To share with us any challenges or questions related to health IT standards, interoperability and data exchange that the Precision Medicine Task Force could address to help you.

For example, what existing standards are you using and are you having any difficulties with them? Are there gaps in standards that you think need to be addressed in order for your course to progress and the like? So, I will then close my preliminary remarks.

As Michelle has mentioned, Leslie Kelly Hall is unable to join us this morning so I'll be the sole Chair for as long as I can hang on, and I will have to ring off in about an hour and the staff will manage the meeting from that point forward. So, without prolonging the introduction any further, I'd like to turn the conversation over to Jim Breeling from the Veterans Health Administration Office of R&D; Jim, thank you for coming.

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

Thanks very much and thanks for the introduction. I think the Million Veteran Program probably dates back to conceptual ideas of a centralized genomic program for the VA sometime around 2007, 2008. The actual...

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

Jim, it's Michelle; I'm sorry to interrupt you. You're a little soft, if there's any way that you could increase your volume.

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

I will try. I'm working with the Hilton Hotel handset here, so. Does that help?

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

Yeah, it's a little better; thank you.

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

Okay. So the MVP program started about 2007, 2008 with a...in concept and actually began executing in the 2010, 2011 timeframe, so it's been operational for now about five years. And we'll talk about where we are now and where we want to go. So, first slide please, which is slide number 10 I think in the deck.

Most recently we've been in communication with folks in the White House about exactly where MVP fits in the PMI vision, both at the White House and NIH level. And that was work that we started last summer, but has extended over the last 12 months, and we've identified some bottom line goals for

MVP to contribute to PMI. We plan to continue enrollment to at least a million, which we expect to hit by the year 2020 and internally the VA has decided to keep on going after reaching a million, so the cohort eventually will be much larger than that, possibly extending to the nine million or so veterans that actively use the VA for healthcare. A lot of that is dependent on resources.

The second major bullet there is to, at the urging of the NIH and the White House to open up the MVP data sets to non-VA investigators. And we have a scaled idea of how that would work, but we're on...we want to reach more than 1000 simultaneous investigators, combined VA and non-VA investigators, by the year 2020. That involves opening up access to the data.

We're going to need a bigger biorepository at that point; our biorepository was designed for four million specimens, but we're in the process of thinking about a fully CLIA-compliant biorepository to allow us to collect specimens that...where we can feed the data, the clinical data back to the hospital care system. And we would need a second biorepository to do that.

And then we're also exploring the ways in which we can turn the genomic results from the science back to the providers and the participants and the veterans themselves. And so those are some of the things we'll touch on as we go through the slide deck. Next slide please, which will be slide 11.

Where are we now? We've currently enrolled more than 450,000 veterans. We're acquiring new enrollees at the rate of about 100,000 a year. We do, in general we do the genotyping on our chip, but we've also sequenced exomes on about 30,000 and whole genomes on about 2000.

Our next set of chemical analysis contracts are going to be put out shortly and we're making some internal decisions about how much whole genome sequencing and exome sequencing we're going to do in the next 500,000 patients that we enroll. And it's highly likely that we'll, because the price has dropped and some of the other information that our genomicists have looked at, we might be doing more whole genome sequencing in the future, having greater value in doing that.

The third bullet, we've established at the urging of our Secretary, an MVP ecosystem that includes public/private partnerships with academia and industry. And we've signed two cooperative research and development agreements so far; one with Lockheed Martin and the other with Seven Bridges, and they're developing some defined artifacts for us on data security, identity authorization, computational architecture, etcetera. And you'll see a slide later on with some of our academic partnerships as well.

The scientific program, doctor...is I believe listening in; she's the scientific program director and they have funded three alpha-test projects and five beta-test projects. We have eight funded research proposals. We call them alpha and beta-test because our scientific platform is...they're just beginning to kick the tires on it and our IT folks will be watching as they begin to use the platform and determine if the high-performance computing cluster that we've built is adequate to the task.

So we wanted to create the right expectations for the scientists as they begin to use the infrastructure, and so we call them test projects in c...so if you have an outage in the cluster we can say, well that's...thanks for testing and we'll try to make sure that the infrastructure works better. And so far we've published three scientific papers in peer review journals. Next slide, slide 12.

These are descriptions of the actively-funded MVP projects. You can see that the alpha projects focused on conditions that veterans' experience and something for which our data set is probably enriched in its

collection. But the beta projects extended to cardiovascular disease, chronic kidney disease, metabolic disease and other disorders. So as we issue more RFIs internally, we expect the number of conditions to...that we're going to be studying to increase.

And you can see some of the affiliations of the investigator consortiums that are a part of these projects. We encourage investigators to form consortiums because of the variety of skills that are needed both in phenotyping and genotyping, so they responded by putting together some nice partnerships with people that are already academically affiliated with the VA. Next slide please, slide 13.

Some information on enrollment; we mail out invitations to participate. We follow that up with a baseline survey that looks at military, occupational, environmental exposure history as well as detailed family history. And especially in the area of what kinds of data types we think that there's a gap, you know, we collect our family history on our survey and so what would really be beneficial here is to make sure that we had a health IT standard for what is a family history and what...how is that data to be structured; so that would be a big contribution of this...in our mind. You can see the number of enrollment rate is about 13%. Next slide please, slide 14.

We enroll at our participant VA Medical Centers, about 50 sites are enrollment sites. We also do enrollment at many of our community-based outpatient clinics and we're looking, we're always looking at new sites to coming on-board. It requires some coordination because you need a dedicated staff at each participant site, an MVP site coordinator and an investigator and backing from the hospital Director, etcetera, etcetera. But these enrollment sites are the ones that are allowing us to enroll that 100,000 patients per year. Next slide, please.

A little bit of information about the chemical analysis, and I'm not an expert in this, I borrowed this slide from people who work on the chemical analysis. Our gene chip is...has 723,000 markers and it's based on our looking at the UK Biobank and other large gene programs, as well as enriched for novel variants, for ethnicity and also some VA custom disease-specific variants. So it's a pretty useful chip for our purposes. Next slide.

Turning now to...away from the genomic data back to the electronic medical record; as people know, we have a fully integrated electronic medical record across the 156 Medical Centers that comprise the Veterans Health Administration. And this describes a little bit about the analytic ecosystem we have. All the hospitals asynchronously replicate their every transaction to a Corporate Data Warehouse, which you see there centered in Austin, Texas.

And so the VistA data coming from our EMR is asynchronously transmitted to the CW. We collect that in about 68 different data domains; things like demographics, laboratory tests, pharmacy orders, all of our text documents. And there are several enclaves that are spun off the Corporate Data Warehouse, including the one, if you can see it, it says Research and Development. That's our VINCI Research Environment where we do research on data modeling. Right now we're implementing the OMOP data model on top of our Corporate Data Warehouse data domains and working on about 50 or so natural language processing routines to process the medical record text documents. Next slide, please.

This is slide 17 and you can see that our electronic medical record data which goes back 20 years, more than 20 years, contains information of great wealth on over 22 million veterans, including 3.2 billion progress notes, orders, pharmacy refills, radiological orders, vital signs, consult notes, admission and discharge notes. And in particular, related to the Cancer Moonshot, we have the pathology

interpretations and the surgical operative notes and the tumor registry entries; that's with the oncology program, 1.3 million tumor registry entrants, which are curated data provided by the cancer registry at the local medical center. So we have a fairly rich amount of clinical data to match up with the genomic data. Next slide, please.

The phenotyping approach we're taking is fairly rigorous. So, as Mike Gaziano, who's the brainchild of the phenotyping strategy will describe, it's a three-tier, seven-step phenotyping process where we take raw data from the Corporate Data Warehouse, bring it into our VINCI research environment, overlay the OMOP data model and then extract data, both from the structured data elements, but also using our NLP tools. And we end up with a qualified phenomic database.

But we...and Dr. Gaziano in particular is very interested in refining the algorithms and making sure that the phenotype is accurate. So there is a separate chart review validation step that is introduced and then the last step is the development of a probabilistic model so that you can identify people who are likely in the phenotype, identify people who qualify based on maybe structured data, but are...have low probability of having the phenotype based on the unstructured data. And we can actually do, for example, GWAS using only people who are the highest likelihood of being in the phenotype and exclude others who may have spuriously qualified for the phenotype, just using the structured data. Next slide, please.

This is a little o...this is slide 19; it's a little bit of a sur...overview of the high-performance computing cluster that we're using. In the GeniSIS data warehouse, we collect all the survey data that we've collected from the enrollees, which as I said before, includes their family history, bits about their military history, their occupational or environmental exposure history, their general level of fitness, etcetera.

We combine that with clinical data from our Corporate Data Warehouse and the VINCI research enclave. We bring in a variety of other data as well from the National Death Index and other registries that are internal to the VA. So we have access to several different data sources besides our electronic medical record, and obviously we combine it with the molecular data we have from our genotyping and our sequencing.

The model in the HPC is that we have an honest broker that understands the identities of all the different data in all the different data sources and given the right consent for an investigator consortium, we spin out a query mart for them to do work preparatory to research. They can see aggregate data that doesn't have personal health identifiers or personally identified information in it. They can understand that there, you know, how many patients in the MVP cohort may be of interest to them.

And then once they've, you know, been awarded the grant, then we spin out a special Study Mart for that investigator-led team and then they have full access to all the qualified cohort data, survey data, the combined other registry data and the molecular data and they can use the HPC to...for the analysis that they intend to perform. Next slide please, slide 20.

We're looking...right now our HPC is internal, inside the VA firewall. We're doing active investigation and high-level architecture conceptualizing of what this would look like in the Cloud. And we're looking at not only receiving the data directly from our sequencing vendors over the wide area...net; right now we receive it by having the vendor ship us an encrypted hard drive which is very manual intensive.

But then having several environments within a Cloud Architecture that allows the data to be indexed and cataloged to be curated and checked for validity then move it into an investigational area as a work preparatory to research area and then finally the Study Mart area where they can mount their data on an expandable computing HPC. So if they need a thousand nodes, we could ask for a thousand nodes, if they don't need any nodes, then they're not using the resource.

And also the long-term data archive, because as we project by 2020, the size of the archi...that data archive could be as large as 100 petabytes, and so it's a significant expense just to even put the data into cold storage and then call it up when it needs to be reused again. And then there has to be information about the security and bringing the genomic variant file that's the result of the investigation back down inside the VA, and that's what the little arrow through the trusted internet connection means down in the lower right-hand side of this slide. Next slide, please.

I'm mindful of the time so I'm going to go a little bit fast. This is the slide that describes some of our industry partners to date and our academic partners to date. Next slide, please. These are some of the deliverables that are...we're looking at the industry partners to provide us. Next slide. These are some of the skill sets that our academic partners are bringing to the table. Next slide, please.

In the final series of slides, we are talking more about the value of MVP to precision medicine and also to directly feed the information back to the veterans themselves. So you can see on the left-hand side, Dr. Rauch will talk about this, our beginning to enroll not only veterans who use VA for health care, but all the veterans, including those who don't use the VA for health care as well as active duty staff from the Department of Defense. We need to move to the secure computational environment that is scalable and open it up to more users, including non-VA investigators and the CLIA-dependent biorepository and then exploring returning the genomic variant data to the clinical decision support system of the future. Next slide.

So our conceptualizing of how that would work, of how we would translate the science into clinical care. Along the horizontal axis here you can see some of the capabilities in terms of storage, compute, networking, privacy, security, the analytics, program management, system integration. But the real heart of the matter involves the seven health verticals; pharmacogenomics, population health screening, carrier testing, rare disease diagnosis, next generation sequencing informed cancer care which I guess you could call precision oncology, genomics influencing chronic disease management and genomics influencing wellness and performance training.

So for example, if you were to find a group of genes that would predispose you...predispose you to say for example obesity and heart disease, you would target those patients for wellness programs and early intervention, before they came obese, for example. Next slide, please.

And so our concept here on slide 26, central to this is our ability to produce what we would call a genomic case file, which would be the genomic data of relevance to the clinical care based on evidence-based research. And you can see the Bio Bank and the chemical analysis and the phenotyping coming in from the electronic medical record, but what one could imagine this genomic case file being a relatively small file.

And we want to be able to bring that file back down inside the VA and then apply our knowledge bases and various APIs to use that case file for discovery and more science, use it for development and, you know things like biomarker validation and diagnostic development. But also use it to deploy for those seven health verticals, pharmacogenomics, precision cancer, etcetera.

And the VA actually is currently engaged in at least one activity where we're beginning to think about how we would use genomic data for clinical care in the mental health world. And we're having some active meetings going on and sort of brainstorming, conceptualizing how would we use that genomic case file to directly influence clinical care in the mental health arena. I think that's the last slide; next slide, please.

Ah, a little bit about interoperability, and Dr. Rauch will probably talk a lot about the Millennium Cohort, so I won't cover that, but we have a project in our VINCI data warehouse, we call it DAVINCI and we've demonstrated in a pilot the ability to bring over health domains from the Department of Defense related to mental health. And we're expanding that to more data domains with the goal of having available in our Corporate Data Warehouse similar data domains from the DoD, which would really facilitate our ability to phenotype...more completely phenotype suitable patients because all, of course all the veterans were active duty at one time.

We also have completed an interagency agreement with the NIH for the Precision Medicine Initiative there to use the MVP recruitment and enrollment engines to recruit and enroll to the NIH cohort. And we're beginning to explore a very...potentially very valuable collaboration with the Department of Energy, using the Department of Energy computer facilities at the National Labs at places like Oak Ridge and Argonne and Livermore to do some of our heaviest, most intensive data modeling and data crunching. And more particularly to explore different platforms and different technology architectures in the use of tremendously large data sets.

So for example our Corporate Data Warehouse right now I believe is...contains the 22 million veterans comprise some two trillion rows of data. And some of the standard computational technologies that we're currently using, we don't expect to be able to continue to use because we acquire several billion rows of new data every year and, as I mentioned before, the chemical analysis we propose to do may end up with as much as 100 petabytes of genomic data in addition. So we really are looking to partner with the Department of Energy to understand some of the most intense horizon scanning for computer science and what's...where...what platform would we be using five years from now.

Now I believe that's the last slide and so I'll stop there.

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

Jim, thank you very much, we really appreciate that overview of the MVP. I did hear you mention that you would benefit from having standards around family history, were there any other specific asks of this particular committee or responses to the questions related to how you use the standards that are available today? What issues, if any, you have with them? And what implementation questions or help you might need?

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

Good question. I think that our electronic health record, you know conforms to a lot of the same standards that others do. So we use LOINC, we have ICD-10, you know, CPT codes; so a lot of our structured data that comes to us I think will comply, in terms of messaging and data...the structured data. We don't see that as a major issue. I think it's the survey information that we collect, you know the

surveys we developed were our own kind of based on models that UK Biobank had and other, I think Kaiser was also looked at.

But that survey information, which includes family history but is not limited to that, includes occupational exposure and environmental exposure, that's kind of an unexplored area, I don't know if we've really validated the accuracy of that. We believe it's more accurate than information we can...we may get from the EMR, for example, but having that produced in a standardized way I think would be of benefit.

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

All right...

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

Are we going to...Andy are we going to take questions now?

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

David, I was going to...I was going to just say that.

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

Okay.

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

I was going to say, are there...for the members of the committee, if you can't use the hand-raising strategy on the App, then just yell. So David, I guess you yelled; if you have a question, then go ahead.

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

Yeah, not surprisingly, I yelled. Jim thanks for an incredibly well organized presentation. That's one of the cleanest, easy to follow presentations I've heard on such a complex space in a long time. I want to pursue the last question about standards and ask you a little bit, if you know anything about what you're doing for the phenotype extraction that you describe, the multi-step process. I assume when you go through all those textural nodes you're pulling out additional information that goes beyond the traditional, you know LOINC encoded lab data and stuff like that.

And I'll bias my question by wondering what you've thought about HPO as a vocabulary to encode the complex phenotypes? If you've considered that or if you're planning to use that or if you've ruled it out, simply because HPO has come into pretty common use for encoding the reference data in the OMIM and things like that, so obviously HPO is non-trivial to use; I'm just curious what your thoughts about that are?

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

Well, you're sort of exceeding my knowledge in that area and I can find an answer from Dr. Gaziano, who would probably be able to answer that. I can tell you that the...we need data models for both the structured and unstructured data, you know the decision to move to OMOP overlaid on top of our raw

CDW data was you know, taken with some consideration. But it in fact is an incredible amount of work, it probably expanded by a factor of two the amount of storage required for the mappings.

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

Hmm.

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

And from...as a technology, more of a technologist than a phenotyper, I would say that, you know that poses a challenge. We, you know we had to massively ramp up our infrastructure just for the OMOP mapping and, you know, I think that you're addressing a very important issue about the unstructured data and the one...we're wrestling with the NLP algorithms as well.

So, you know most of the NLP algorithms we get are open source tools that have been developed, you know at our university affiliates or come from academics and they've been proofed or tested on say the largest data set that that investigator can access, which in many cases is, you know say 5000 progress notes. And then when we attempt to take that open source tool and run it on three billion progress notes, it presents an incredible problem. And that's one of the reasons why we're looking at Department of Energy and some of their computing capability, just from the sheer size of our data.

So, you know, I don't know much about HPO, but I would imagine we're going to have to wrestle with that problem when it comes to standards coming out of that. As we improve our NLP capability and mine the unstructured data more completely, we're going to have to model exactly what that data means and where it fits in in the phenotype.

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

Ah great, thanks I appreciate that.

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

I have a question...

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

Thank you, Jim. Dixie, go ahead.

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

Yeah, thank you; this is Dixie Baker. Umm, you mentioned, and I agree with David, this was just a fantastic presentation, very, very clear and extremely interesting. I had a question about the consent and what kind of consent are you asking them for, what's the granularity of consent? And how do you persist a consent and connect it, you know associate it with the data?

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

Good question and I didn't include anything about that, but the consent was carefully considered. It's fairly broad so it includes reuse of the data and it also includes our...their agreeing to use re-contacting them to get additional information; whether that's an additional biological specimen, it would include, for example if we did a cohort of prostate cancer and we identified people in MVP that were...had the phenotype of prostate cancer, it would include permission for us to go and go back to the hospital and

get the tissue block of the prostate cancer cells and submit that for chemical analysis. So, it's a fairly broad reuse and re-contact consent.

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

So is it a paper consent or is it electronic or what?

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

It...right now it's a paper consent that we scan and digitize. Umm, we're beginning to implement, umm electronic consenting. There's an identity authorization step there that we're working out, but we think we can solve and we would like to be able to move our consenting from the paper form that we scan to say a tablet form factor where the patient may read it and digitally sign it and then electronically transmit it. So that's...the recruitment and enrollment engine that we've used is paper-based, based on mailing, you know people a postcard and having them come in and signing consent form in person.

We're beginning to architect a system for doing recruitment enrollment engagement, in other words, scheduling the patients for their blood draws and clinic visits as well as feedback, feeding back to them data that they might find useful. So that second generation recruitment and enrollment system would include the engagement and the feedback loop as well.

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

Mm-hmm. And the reuse is reuse for what?

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

The reuse would be for any sub-study that we would maybe spawn up. So for example...

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

...this is for research.

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

For research, right.

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

I see, I see.

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

So the consent form for the next 500,000, you know first we have to get the step of the CLIA-certified biorepository, but the next step beyond that would be changing the consent to include clinical use of their data and how we would, you know, feed that back. We already have in the VA a system of clinical genomics counselors and interestingly enough, we do our genetic counseling by telemedicine. So we have about two dozen certified genetic counselors and...but they're not distributed at the 156 VA Medical Centers, they're mainly in our Salt Lake City VA.

And we...if a clinic needs a genomics consult, they place that consult electronically and they schedule the patient for a clinic visit and the visit is performed via telemedicine back to the certified genomics counselor in Salt Lake City. So we would have to greatly expand that system.

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

Okay, thank you.

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

Dixie, thank you. Thank you, Jim for the answers. Any other questions for Jim?

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

Hi, this is Eric Rose; a very quick question. Thanks for the presentation, fascinating. You mention that family history data would be important and one thing, this is a bit in the weeds but, one thing that would be interesting is your perspective on the representation of familial relationships and how detailed that needs to be. You know, that is to say if a patient has a family history of Hodgkin's lymphoma, what was the specific relative that...what's the relationship of the relative that had that and do you really need pedigree data which is to say, identifying the specific individual so different bits of family history can be identified pertaining to the same individual human relative?

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

Great question and again, you know, that's where Dr. Larry Meyer, who is our medical genomic program director for those genomic counselors that we have for our telemedicine program, that's where his expertise lies. And I believe that he has been working with NIH and ONC in another project to adopt that family history standard, including pedigree, into some sort of national standard. And I apologize, I should have reached back to him for this presentation, but I believe he's working on that issue or the VAs contribution of that issue to the national standard, I just don't know what it is.

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

Thank you, I will say that...this is Andy, that there is an interesting coincidence that, at least it's a coincidence, it may be not a coincidence that your genomics counselors are in Salt Lake City where perhaps the largest database of ancestral pedigrees in the world resides.

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

Yeah, it's not a coincidence, it's not a coincidence.

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

So, you know if anybody has a set of standards for how to characterize pedigree and what's associated with a pedigree they will. Good.

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

Yeah.

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

Other questions, otherwise I think I'm feeling the need to move on.

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

Yes. Okay, Andy, this is Mitra Rocca, I have a quick question.

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

All right.

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

So this is Mitra Rocca from FDA and I have a quick question. Jim, on slide 24 you mentioned that you, for the MVA participation you said VA and DoD data for active duty staff. Do you also use the family members' electronic health records from DoD active duty members or only active duty...

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

Right, so that data transfer from the DoD is, Dr. Rauch will explain how we're doing it. We're beginning to think about doing it for the Millennium Cohort and I explained a little bit about the experimental design in the DAVINCI Project. We're not in production with that yet, and that needs to scale up over the next 12 to 24 months to a production level, you know, data transfer and I don't believe that it includes family members, but that is a data gap, yes, you're right.

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

Okay, good. Thanks

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

Thank you. Michelle and gang, I think we should move on to Dr. Rauch. I don't know if, Dr. Rauch, are you on the line?

Terry M. Rauch, PhD – Director of Research & Development, Policy & Oversight Office of the Assistant Secretary of Defense – US Department of Defense

Yeah, I'm on, can you hear me?

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

Yes we can and the microphone is yours.

Terry M. Rauch, PhD – Director of Research & Development, Policy & Oversight Office of the Assistant Secretary of Defense – US Department of Defense

Oh...

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

And Michelle, before we let Dr. Rauch go on, as you know, I'm going to have to drop off in a few minutes so if there's a speaking gap, where you need a Chair to talk, fill it.

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

Yes. We...we'll take care of it, thank you, Andy.

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

All right, thank you. All right, go ahead Dr. Rauch, sorry.

Terry M. Rauch, PhD – Director of Research & Development, Policy & Oversight Office of the Assistant Secretary of Defense – US Department of Defense

Okay, so I guess as a prelude to this, let me just say that we in the Department of Defense have...are supporting a lot of individual research projects that are associated with genomics and precision medicine. We probably have, you know, over 200 individual research projects that address anything ranging from, you know genetic variability in response to malaria treatment to OMIC biomarkers for traumatic brain injury in PTS...in response to PTSD treatments or even, you know, acute trauma and risk for coagulopathy.

So, we have a pretty broad OMIC research program, but in the spirit of the President's Precision Medicine Initiative and specifically the quest to establish a national research cohort, we and early on, early last year started talking with the VA because I knew that the VA had the Million Veteran Program and the associated infrastructure with the Million Veteran Program and I thought that probably the most efficient way for us to take a first step in the President's Precision Medicine Initiative was to use the Million Veteran Program to the fullest extent that we could.

Now, within the Department of Defense...you can go on to the next slide, yeah. So, within the Department of Defense, we have a...our largest cohort study is the Millennium Cohort Study. And that's a study that's been ongoing since probably the early 2000 timeframe. It was in response to Congressional Direction and kind of the overall theme to the Millennium Cohort Study is to umm, research umm, and document umm, military experiences and how they affect health outcome in our service members. And then, actually our most recent panel was to look at the military experience and its effect on health outcomes in military family members.

So, umm kind of the bottom line up front is that we thought that using the Millennium Cohort Study and the enrollees and offering them the opportunity to enroll in the MVP would kind of serve two purposes. Number one, it would help both DoD and VA, particularly VA to continue to build towards their Million Veteran Program and it would also, for us, kind of you know contribute to this continuum that's needed between the DoD and VA where our population in the DoD is going to become the population in the VA, and we need to assure interoperability and also the continuum of data flow, research data flow from the DoD into the VA. So, let's go to the next slide.

So a little bit about the Millennium Cohort Study; like I said, it's been ongoing for quite some time. It's composed with numerous panels. It not only includes active duty but also includes Reserve and Guard. You will see that it has a broad, kind of a broad mandate when it looks at the military experience and various health outcomes that you can see on slide 31.

If you go on to the next slide; the participants are surveyed at about 3-year intervals; 45% of the participants are affiliated with Army service, a little less than a third with Air Force, little smaller percent's with Navy and Marine Corps. We have more than half, 66% were on active duty and the

remainder consisted of Guard and Reserve personnel. Sixty-two percent of the participants in the database deployed at least once in support of the wars in Iraq and Afghanistan and we have a pretty sizeable population of enrollees that are women; I can't remember the exact percent off the top of my head, I think it's certainly at least a third.

So, one comment that I will make on the value of our contribution into the MVP, I think if you look at the MVP database, it's pretty heavily focused their enrollment in Vietnam era veterans, so by this...by our participation I think we will potentially create a relatively robust database that will include younger enrollees that get to the veterans of Iraq and Afghanistan wars. I think that MVP probably is very, very well represented with males, but I think with our population and our participation, we can increase that database with female representation also.

Okay, so if we go to the next slide. So one of the first things that we wanted to do in our collaboration with the VA is work with them and determine who do we have in the Millennium Cohort Study that might also be enrolled in the Million Veteran Program. And so we did that and we also wanted to know kind of relatively quickly, a quick scrub of who we have in the Millennium Cohort database that is living relatively near to an MVP enrollment site. Because that was critical for us to determine because we...in DoD we don't want to really reinvent, you know the MVP infrastructure for our purposes, we want to leverage it.

And so you can see that we've identified those that are already currently enrolled in the MVP that are also enrolled in the Millennium Cohort and we've also identified a population that we could offer, a veteran population that's in the Millennium Cohort that we can offer enrollment in the...into the Million Veteran Program. So, if we go on to the next slide.

It still leaves us with a very sizeable part of the Millennium Cohort population that's not enrolled in the MVP and so our continuing work with the VA is to identify those individuals and on a phased...woops, and on a phased basis, my screen just timed out so I got to try to...I got to log in for...re-log in for a second; bear with me because my screen just went blank, now I'm back up. And so we're working with the VA to...on a multiphase process and offer enrollment of Millennium Cohort enrollees that are veterans in phasing all the way to offering enrollment to active duty. Go to the next slide.

Umm, pretty much already talked about that, I think we can go to the next slide. These are the four phases of the plan, which we've really already started, but as you can see, they progress over the four phases to eventually offer active duty enrollees recruitment into the MVP and then eventually add on some DoD enrollment sites into the MVP infrastructure. Next slide.

So a bit about data coordination; basically expanding the MVP to include non-VA data from our sources and in addition, supplying you know, a history of military experience and service related exposures and disabilities, also other phenotypic databases that could be accessed by the VA. Next slide.

And that's basically it. I can entertain any questions that you might have.

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

Wow, silence. Thank you so much. Any questions from our task force members?

Terry M. Rauch, PhD – Director of Research & Development, Policy & Oversight Office of the Assistant Secretary of Defense – US Department of Defense

Good, I'm off...

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

Sorry. Well, if there aren't any questions, we might be finished quicker than we thought.

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

I have a question, Steven here, I'm sorry.

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

Hi, Steven; go for it, thank you.

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

Yeah and this relates to the first speaker as well. In terms of getting the data back, they said there was some way for getting clinical results back, I was curious, is there any way to get the research data back and do the patients have control over it if they wanted to say, you know contribute it to the Personal Genome Project or with their own tools or do they only have access to a clinical genome kind of counselors?

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

Within the VA we don't provide them any information back yet, it's really the...it's posed to them as a research project as a research...and a research consent. And as I said, we're...for the next 500,000 patients, we're looking at changing the consent and developing infrastructure for delivering results back to them.

And I think that one of the agreements with the NIH is that umm, veterans can opt to join the NIH cohort as well, and we're...you know, so we're going to be taking...of the group of 100,000 people that we enroll annually, obviously based on what Dr. Rauch is saying, we're projecting that that number will go up because we're going to be including DoD folks, so let's say it's 120,000 you know, or more a year. Right now the agreement I believe we're arriving with the NIH is that 10,000...we will use our machinery to enroll 10,000 people a year into the NIH cohort. It may involve having dual consent and the patient signing two consent forms and two tubes of blood, but I actually don't have the details, but that's a possibility. And in addition, somebody can, any American evidently will be able to be involved in sort of the one...the individual initiative, that's not necessarily precluded to them, I think.

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

Okay, thank you. When you say that, when you say returning results in that way, are you also talking about the raw data or are you just talking about send the relevant results?

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

That's under study; right now we don't think that we would give them the raw data, but that's an open question that's being discussed. Umm you know, what I'm talking about in the sort of those seven pillars of health...

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

Right.

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

...umm, health outcomes that we hope to impact, what we would be doing is delivering a genomic variant file to a knowledge engine in a clinical decision support system that then would deliver, at the point of care, information that both the patient and the clinician, the provider would need to know. So, in that scenario we're not saying okay...to the patient, you can see the raw data, but what we would be saying is that when you go to your provider and you get care, your care would be informed by your genomic data.

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

Do you think there would be a way for people who wanted to be engaged and as an incentive, they could be able to have ropes to access the raw data?

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

Absolutely, I mean, and that's why it's an active issue that we're studying. You know, it can be for those patients who want to be involved, we're entirely open to that possibility and hope to design systems that will accommodate that. But we're also aware that, you know, for many people it would be confusing, you know.

I don't know about other people's practice, I've had some, not lately but bef...in my other life I had some practice experience and I've had the experience of people bringing in a CD or a DVD of, you know, various other information that they've obtained; in this case it would be genomic data, and saying, I have this DVD, can you review it and tell me if I'm going to get Alzheimer's and, you know, that's a problem for our providers. So the question is, how do we introduce that information in a beneficial way both for the provider and the patient so that the interaction is the best one it can, you know, that improves outcomes and lowers costs as opposed...

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

I mean, I think it could be good to look at, you know, for example a...understanding of Genome Project or 23andMe or...microbiome site where, you know, they'll give you a kind of a clinical type results data that's easy to understand but you can also have the option to download the raw data.

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

Right.

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

But I think that makes a big difference, even if 99% of people don't have access to it, but they know that it's there if they want it and they can then share it with other researchers and be able to have, you know as an incentive I think it's really powerful to have that.

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

Yup. I can tell you that on April first we're having our...we've been planning it for a while but it's our first internal VA discussion about clinical precision mental health.

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

Right.

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

And that's one of the first issues we grapple. In the mental health world, where you know there may be pharmacogenomic information and family history information and what do we directly share with the patient or the patient's family and what do we feed into that knowledge engine that the provider and the patient may interact with. So that's something we're actively interested in, I totally appreciate your question.

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

Okay, great. Thanks.

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

And David McCallie with another question, maybe more for Jim; did the, you talked about the genomic case repository and I wasn't quite clear on that. It sounded at least a little bit like maybe the subset of the genomic data that was thought to be relevant and important, sort of the variants that matter. Did I get that right or did you mean something different?

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

Correct. Correct and this is a concept, it's not an actual thing that we have at the moment, but the you know, the concept is is that there would be, over time, solid science behind what some of the variants meant and...including how they could best be used to improve outcomes and lower costs.

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

Mm-hmm.

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

So where there was evidence-based approach and solid science behind the use of a particular variant information or particular, you know mutation or insertion deletion gene copy, whatever. Where there was solid science, there would...that would be added to this case file and then the clinical decision support system, you know say when the provider sat down in clinic with the patient opposite them, and

they opened up the electronic you know cover sheet of the electronic chart, everything there would be guided by that knowledge. What drugs the provider should order, what adverse drug interactions or drug-drug interactions might be you know, looked for, what screening should be offered, you know, etcetera. So that you wouldn't have every mutation in that case file, you would have the ones that this state of the evidence-based medicine was such that it was important to drive clinical thinking.

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

Yeah, that's...I love that and I think as a EHR vendor we struggle with the question of what parts of the genomic data belong back in the EHR in structured form because clearly you don't need all of it, you don't need the BAM and FASTQ files. You probably don't need the full set of variant calls, you know at the level of the four or five million per patient, but somewhere there's a subset of stuff that, you know we call them biomarkers, but that's probably the wrong term, of the stuff that's important enough to actually structure and capture in the record and expose to local decision support tools. I mean, it in my opinion is a crying place for where we need some standards to emerge because there's not agreement on how to represent that data today, much less on what data needs to actually be there, but...

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

Right, you're probably very right...

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

I think...yeah...

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

...that's probably straight on.

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

Good, thanks.

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

Could I follow up his question with an...I kind of interpreted what you said when you were briefing that slide Jim is that the genomic case file would be something that would be consumed by the clinical decision support module versus a human being. Is that right or is this, you know, what you just described sounds more like something you give to a human being instead of clinical decision support ?

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

No, no, I think it's consumed by the clinical decision support system, but it's immediately available when you open up the individual electronic record.

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

And as a case file, it's not just like, you know, refer him to such and such or...it's not just a dec...a recommendation of a decision it's actually a case, you know, some kind of file to look at.

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

Yeah, we don't know yet so...

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

Oh.

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

...you know, that's something that we're, at least from the MVP program would, you know deliver this genomic case file and the EMR of the future, let's call it, would consume it.

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

Dixie, from...this is David; from our perspective we kind of think you need both of those...

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

Yeah, some...yes.

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

...something that's, yeah, human readable but also structured enough to drive decision support; like you might have, you know hypometabolizer of antidepressant class, you know, as a human readable string, but you need the actual deep logic to know which drugs are actually affected...

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

Yes, yes...

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

...metabolism.

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

And the case file would give you the context for the...yeah, I see. Yeah, that's good.

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

Yup.

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

That's interesting, yeah.

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

And, you know, one issue about the case file though is that it's highly dependent on the state of science so if you produce a case file and 12 months from now the science indicates that the information you've put into the case file is say, entirely wrong...

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

Mm.

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

...your clinical decision support system will be driven by information that's no longer accurate and up-to-date. So, within the...somewhere in the system, there has to be a group of experts that continue to look

at the information that's in the genomic case file and keep it up-to-date; that's going to be an incredibly different...difficult problem.

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

Yeah, agreed. Thank you.

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

(Indiscernible)

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

In the absence of any other comments I'll just add one more tag-on to the last conversation. The way we think about that is that it's probably a Cloud-based service that would be where you'd keep the knowledge up-to-date rather than trying to push it out to every individual EHRs decision support system, just because of the rapid changing nature and the scale and scope of the data. So you might store the data in the patient's record, but you might actually query a more central service to see if there's some relevance for a particular drug that you're about to prescribe or a particular lab test that you're trying to interpret.

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

Great idea, I love it, I love it. And then you would have an API that reaches out to that service and...

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

Yeah.

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

Yeah. Yes.

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

...wonderful idea, I'm loving it.

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

Good.

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

Good.

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

Any other questions from the task force? Okay, well thank you so much to both of our presenters, we really appreciate it. Lonnie, can you go back, I think its slide 6 with the work plan on it? Umm, yeah. So, thank you all again and so when we get Leslie and Andy back together we'll work on a summary of today's discussion and then during our next call on Weds. March 31, I'm sorry, we will focus...we will have presentations from FDA and focus on the FDA. And then also have patient rights and ownership of genomic pattern data.

And so with that, if there is no other question, we'll go to public comment.

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

Mm, hey Michelle...

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

Hey, this is Maya...

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

Oh sorry, go ahead.

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

Yes, I'll follow you, Maya.

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

Okay, just really quick note. There was interest expressed in some correlation between this group and the API Security Task Force, which is another concurrent effort that ONC is running. Some people had reached out to me separately just saying that there appears to be some overlap. I think if there's interest, and folks on the phone just let me know either right now or you can shoot me an e-mail; if you guys are interested in getting a read-out of what that task force is accomplishing, given potential intersections with Sync for Science and some of the other things that we've heard from NIH, I would be happy to set that up, too in an upcoming meeting. So, let me know if that's interesting to you all.

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

Yes, I would be interested; this is David speaking.

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

Yeah, me...

Maya Uppaluru, JD – Policy Analyst for Health Innovation, Division of Science & Innovation – Office of the National Coordinator for Health Information Technology – Department of Health & Human Service

Great, I'll take that as a yes.

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

I do too as well, yeah, Steven, thanks.

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

Maya, this is Michelle; we can talk about it offline but I think it might make more sense to have them share with the group once they get closer to final recommendations of their work.

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

Yeah, that's fine. That's fine, too.

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

Okay.

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

(Indiscernible)

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

We'll follow up and make sure that we share something with this group. Thank you, Maya. Eric Rose, did you have a comment?

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

Yeah, well I had two quick questions. I didn't actually hear on the roll whether Andy and Leslie are...they were both on?

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

Andy was on for most of the meeting but he had...

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

And then he had to drop off.

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

...to drop at the very end.

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

Okay, all right. Well, so I'll save that question for when they're on, it was more of like I wanted to get their thoughts on what should the task force be thinking about in terms of the ultimate trajectory towards final recommendations for the Standards Committee. And by the way, it's really helpful to have in the slides each time those slides on the task force charge and the overall work plan.

My second question though is to the group and I think I'm probably not the only one at these...as we hear these experts speak here about scientific concepts that I'm not completely familiar with like, you know things like EQTL markers was one of the things that came up today. So I'm wondering if anybody has found like a genomics for dummies kind of resource; something that we can go to to just to get a little bit more understanding of some of the precision medicine concepts, the scientific concepts that we hear about to make sure that we're not entirely ignorant about them.

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

Hey, so this is Maya; that's a really great question. So when I first started working on PMI about 10 months ago, I tried to find the exact same resource data you're describing right now. There are a couple of documents that NIH has. I also would recommend the NIH Advisory Committee report that they came out with in September. So, I can work with Michelle to compile some resources like that and we can distribute to the group.

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

Thank you very much, that would be super helpful.

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

Of course.

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

Eric, there actually is a genomics for dummies, by the way.

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

Is there really, in the dummy series?

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

Yes, yes; it's pretty...

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

Ohhkay, I may have to get that.

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

(Indiscernible)

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

That's good to know.

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

Just don't tell anybody that you got it.

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

Yeah, yeah, put a book cover on it when you're reading it in public.

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

Okay, any other questions? Okay, Lonnie, can we open up to public comment?

Public Comments

Lonnie Moore – Virtual Meetings Specialist – 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

Okay, it looks like we have no public comment. So thank you all and we'll talk to you on March 30.

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

Great, thank you. Bye, bye.

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

Thank you.

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

Thank you.

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

Bye, bye.