



Health IT Standards Committee

2017 Interoperability Standards Advisory Task Force

Final Transcript

May 23, 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 2017 Interoperability Standards Advisory Task Force. This is a public call and there will be time for public comment at the end of the 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. Kim Nolen?

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

Hi, Michelle, I'm here.

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

Hi, Kim. Rich Elmore?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Hi, Michelle.

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

Hi, Rich. Christina?

Christina Caraballo, MBA – Senior Healthcare Strategist – Get Real Health

I'm here.

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

Oh, hi, Christina.

Christina Caraballo, MBA – Senior Healthcare Strategist – Get Real Health

Hello.

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

Christopher Hills?

Christopher J. Hills – Team Lead, Standards Engagement Team – DoD/VA Interagency Program Office

Hello, Michelle, I'm here.

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

Hi, Christopher. Clem McDonald?

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Here.

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

Hi, Clem. Dale Nordenberg? Dan Vreeman? 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. Eric Heflin?

Eric Heflin – Chief Technology Officer – Sequoia Project/HIETexas

I'm here.

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

Hi, Eric. Kin Wah Fung?

Kin Wah Fung, MD, MSc, MA – Staff Scientist, Lister Hill National Center for Biomedical Communications, National Library of Medicine

Hi, Michelle, I'm here.

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

Hi, Kin Wah. Mark Roche?

Mark Roche, MD, MSMI – Chief Medical Information Officer – Avanti iHealth

I'm here.

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

Hi, Mark. Michael Buck? Michael Ibara?

Michael A. Ibara, Pharm.D. – Private Consultant – Michael Ibara, LLC

I'm here.

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

Hi, Michael. Robert Irwin? Russ Leftwich?

Russell Leftwich, MD – Senior Clinical Advisor, Interoperability – InterSystems

I'm here.

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

Hi, Russ. Susan Matney?

Susan Matney, PhD, RNC-OB, FAAN – Senior Medical Informaticist – Intermountain Healthcare

I'm here.

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

Hi, Susan and Tone Southerland?

Tone Southerland – Director of Implementation – Ready Computing; Co-Chair, eHealth Exchange Testing Workgroup – The Sequoia Project

Hi, I'm here.

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

Hi, Tone. And from ONC do we have Brett Andriesen?

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

Brett's here.

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

Hi, Brett. Nona Hall?

Nona Hall – Chief, Standards Adoption Monitoring & Reporting Division – DoD/VA Interagency Program Office

I'm here.

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

Hi, Nona. Anyone else from ONC on the line? Okay, with that I'll turn it over to you Kim and Rich.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Okay, thanks, Michelle. Kim did you want to kick us off?

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

Sure, thanks everybody for joining us back. I'm going to be a little bit silent today because I am in my car somewhere between Georgia and Tennessee and I'm pulled over to take this call, but, thank you, and we look forward to the discussion and trying to achieve our new charge that we talked about last week.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

And this is Rich, and so, first of all the original call that we had of this Task Force, we got some feedback which we thought was important to try and understand and make sure that we set up the Task Force in a way that made sense. Based on that feedback we had an administrative call last week of the Task Force, this is the first public call since then, so we will go over, you know, a revision to the charge that we've discussed with ONC and Task Force members, certainly welcome any public comment on that at the appropriate time in the conversation.

And we're looking forward also, on this call, to be able to give you an update, a better update on public comments since that was one of the things that we received some guidance and wanted to make sure we dug into those. Those will all...the more complete list of public comments will be made available to the Task Force I believe by the end of this week was the goal. But we will at least have some level setting for you on what is in there and then all of the comments by the end of the week.

And then we are hoping also to discuss with you and get feedback on some of what we heard in terms of recommendations and areas for improvement in the ISA as it relates to scope, structure and, you know, the characteristics that are currently identified associated with each standard and also this notion of best available, some of that best available conversation will probably go into next week. But that's the basic framing of today and I think we can go onto the next slide.

This is the membership and then the next chart is the official members. Okay, so we have changed slightly the schedule and this will kind of get back to the charge, which we'll discuss in a minute, but basically the idea is that between now and June 23rd, about a month from now, we want to try and get our draft findings and recommendations on those areas related to ISA framing and structure, and any structural improvements, what we recommend as it relates to the concept of best available and updates that we would want to recommend based on public comments out to the HIT Standards Committee and then from there onto ONC to fit in with the timing for the 2017 work that ONC has to then start on for the ISA.

Then once we've done that and you'll see this also in the charge, once we've done that then we're going to come back around, the Task Force will come back around to say, are there, you know, additional updates that we've received from public comments that we want to make some recommendations on or any refinements to those recommendations and we'll present final findings and recommendations to the Standards Committee towards the end of July.

So, those are the two milestones on the initial tranches then after that, and I think we had discussed on our first call, where are there gap areas, you know, additional kind of areas that we think should be worked on going into 2017 and the Task Force will weigh in on those and that will be subsequent to these, you know, these initial set of findings and recommendations out of the Task Force. So, we can go onto the next chart.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Could you just remind us what the deadline is for the written responses you asked about last week? Is that like the 13th or something?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

So, I think that the sooner you can get them in the better. I think what you have here now, if you can go back one slide, please, just looking at the schedule, you know, we're going to be discussing framing and structural improvements today, so we'd be interested in your feedback on that today if you have something after this we can still accommodate it.

Next week we want to try and zero in more on the best available or the next call we want to try and really focus in on best available and what do we interpret that to mean and how would it apply to the ISA.

And then the next two sessions are designed to accommodate feedback on public comments. So, I would say, as it relates to the original request which was basically around structure, framing and best available areas for improvement that conversation will start today, if you have input that you'd like to make sure that we've organized into our conversations with the Task Force please get that to us as soon as possible.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well, I mean, there are physical limits and I thought we discussed that you'd like to have sort of written things so you could work it in without having the tumultuous, you know, the voice conversations as much, but maybe I misunderstood.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Yes, we would absolutely find that to be helpful Clem, you know, produce it when you can, we'll be starting some of that conversation today.

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

So, Rich, do you think we just say by the end of the month or...and then that way that would give us time for the June 2nd and June 14th one to work those in?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Sure.

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

Okay. Will that work Clem if we say the 31st? Did I lose y'all?

Eric Heflin – Chief Technology Officer – Sequoia Project/HIETexas

This is Eric, it will be hard, but we'll try or I'll try.

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

You may have lost Clem. Clem we aren't hearing you if you're talking.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

No, no I'm still here. I'm still here, should I have reacted?

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

Well, she asked if the 31st was an okay date to get your comments in, the end of the month. Clem?

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Sorry, I was on mute, yes, I can do that, sorry.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Okay, great, well, let's move ahead then to the next slide and then I think one more. So, this is the original Task Force charge, go ahead onto the next slide, please. And basically the goal was to...the goal is to be able to think about the Interoperability Standards Advisory and its process in a way that could support the following kinds of uses.

So, this is some of the feedback that we got from ONC as they were thinking about what is it that they were, you know, asking from the Task Force and they bucketed it into these four different categories, providing an open and transparent process to vet standards and attribute them to particular interoperability needs.

The second is to facilitate greater standards use consistency and really trying to level the playing field and expectations amongst both developers and newer entrants into healthcare.

The third is to enable executives that are leading procurements to be able to point to vetted ISA standards so that they have, you know, a reference point that they can use for procurement and standards that they think should be applied for their particular activity.

And then the last is to lead industry dialogue around standards implementation and use such that the government agencies would be able to use ISA as a basis from which to propose regulatory requirements and changes.

So, you know, really the question here is when does an emerging standard become ready for prime-time and are there signals of that, you know, some of this will get into the best available conversation that we'll have next time we're together, but, you know, giving a foundation for, you know, what do we think that are ready for, you know, broader use, more regulatory guided use within the community. So, those were the four that ONC came up with.

Moving onto the next charge just to kind of help you with the overall framing here and what we've been asked to do is to develop recommendations in two phases. The first one we talked about was between now and July, so basically taking a look at public comments and from those figuring out what it is we want to recommend in terms of improvements.

The second, we'll start some of that conversation today, also is related to structural and framing improvements to the ISA including elements that could provide additional clarity or context for stakeholders that would be using the ISA.

The third is a limited set of new interoperability needs that should be included in the ISA along with attributed standards and implementation specifications, so if there is, you know, something that, you know, we think needs to be addressed, you know, as a result of industry transitions or standards evolution that we think is important to get in here we have an opportunity to make those recommendations now.

The explicit best available designation where appropriate, where should that be applied and, you know, in consideration of available implementation experience that this team has either directly or also has, you know, through the resources that you have available to you can help us to offer an informed opinion on those standards.

So, then the second phase, which will be beyond July, is basically to discuss and recommend, from some of the earlier conversations around, what other priorities are there for standards that should probably be included in the projected addition section, you know, what is it that's coming up that we may want to see added to the ISA. So, that will be, you know, kind of July, dates to be determined, but kind of July end of the fall kind of timeframe for the Task Force.

So, that is the basic charge. Let me stop there for a minute and see if there are questions or comments on that?

Daniel J. Vreeman, PT, DPT, MSc – Research Scientist – Regenstrief Institute

Hi, this is Dan Vreeman, I joined a little late, my question here is I noticed the section where we might talk about things to be added to the sort of upcoming future things, I didn't see a specific place to comment on the things that are already in that projected additions place and whether we want to sort of weigh in on whether they should be promoted or left as is or even taken off of that sort of on deck circle.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Yeah, so I think that...Dan that's a good question, so I think that this would probably fall under the category of, you know, limited set of new interoperability needs and that would be certainly a place for us to look in terms of elements that we think should be brought into the ISA more fully.

Daniel J. Vreeman, PT, DPT, MSc – Research Scientist – Regenstrief Institute

Okay.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

You know the...

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Okay, so, we're...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

The challenge you've got, you probably know it all well enough, is that you get stuff that's bigger than a breadbox and stuff that's, you know, sort of microscopic and the quality of sort of the setup isn't the same across all of them. So, I'd say, you know, I think actually I've just been relooking at them, probably

80-90% of them are pretty okay and if you could just tweak them a little bit maybe we could come up with a better answer to what we call it best available or things we heard of.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Great, Clem, hold that thought for a just a minute because when we get to the conversation about, you know, structure and reframing I think that's a really important topic. So, we'll get to you in just a minute on that and what we first wanted to do was to give you the overview not all of the details but give you a better representative overview of the public comments that we received, you know, more details to follow for the Task Force but I'm going to turn this over to Brett, were you going to walk us through this?

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

Yes, I can walk us through. Can you guys hear me okay?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Yes.

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

Yes.

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

Excellent, so first we are going to start on the next slide here with comments that we received or I'll jump back and say, this is really a summary level view and kind of condensed and consolidated list of the public comments that we received this round specific for the ISA scope. They are fairly high-level so if you are interested in kind of seeing some more of the details on what these specifically mean we are going to be sending around to the Task Force members a spreadsheet that contains close to probably 400-500 lines or rows of comments that represent kind of specific actions that the group has received and sorted by different interoperability needs and by sections.

So, the hope is that the group will have those in front of them and be able to sort them by the areas of focus that they are particularly interested in and have kind of a full list of those comments. So, we'll be sending those out as Rich mentioned sometime this week so you will have a little bit more detail.

But the high-level stuff, so the ISA scope, some recommendations to include advice for best available standards kind of beyond just that primary use but also for secondary use and making references to each standard kind of whether it supports kind of the primary or secondary use or both.

A strong recommendation to see, included as part of the scope, patient identity matching as folks felt that with a lack of that it was a huge barrier to interoperability overall.

Another comment here, the advisory should concentrate on promising standards that have significant potential to be finalized, moved into production and widely adopted in the near future, so those balloted standards rather than just kind of duplicating a list of fully mature standards that are widely implemented which generally occur or are bound in regulations and could be published elsewhere.

Another recommendation is to revise the document to include best available standards to deliver that intact vital clinical context and content relationships from their source especially for those primary uses and users.

A recommendation to tie the ISA and incorporate lessons learned specifically from the ONC tech lab and particularly kind of tying to the interoperability proving ground that ONC has developed as part of that effort as well.

And then folks, a number of folks did provide comments around the choice at this time not to include administrative standards and that might be something we want to consider as well as kind of this concept as the advisory over time should become a predictor of what would be endorsed for national adoption and consider adding standards that didn't make it into the most recent certification requirements to kind of clarify whether or not those are still being considered for future certification rules or for wider spread adoption by industry as well.

So, before we go onto the next few slides, which we'll outline similar comments around structure, the six characteristics and kind of start our discussion on the concept of best available I thought, Rich and Kim I don't know if you agree, but maybe we would take a few minutes open it up for Task Force discussion and the group can kind of noodle on some of these and if there are additional recommendations they want to propose we can go that direction.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well, is this one slide from one person or this sort of summary of a number of comments?

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

This is a summary of a number of comments and trying to pull out kind of the high-level themes just to have something for you all to react to here.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

But there...yeah, we could spend a lot of time on it I'm afraid they're all over the...they are going in all different directions.

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

But this is David, one thing that jumps out is clarification on the broad use cases for which the ISA is targeted. So, you've got one question here about secondary use, which I assume means research and other post HIPAA uses and you've got one question about administrative uses. So, if you lump those two together and say, one of the questions is should the ISA be more expansive than just the stuff that's involved in certified EHR to include these things like research and administrative uses or not and we can debate that, but it seems to me that's a valid question.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well do you think that would be like X12 for administrative?

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

Well it's...yeah, exactly billing, you know, weedy stuff, anything, you know, that's not part of certified EHR technology.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well, I'm of two minds, one is that, yeah because it is really used but the other one is we've got so much stuff to digest already that we may drown.

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

Yeah, I'm not...I don't have an opinion but it's a question that should be probably addressed in a preamble is to say what is and what isn't included in the ISA. You could, you know, you could include everything in there because it's all relevant at some level. But maybe the focus should be on, you know, clinical care and if so call that out.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

I guess...this identity matching is an important dimension, it's sort of touched on by what's allowed or not allowed in the patient registration fields.

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

Yeah.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

So, it has already touched and...

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

Yeah, my comment on that one is that it's not really a standard. I mean, no one has defined a standard around that.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well that's true.

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

So, I don't know what you would include if you did include it.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Right, yeah.

Susan Matney, PhD, RNC-OB, FAAN – Senior Medical Informaticist – Intermountain Healthcare

And this is Susan Matney, I like Dave's idea of just honing in initially on what's included in an EHR and that kind of addresses the first bullet where we look at best available for primary and secondary we could say, at this point in time we looked at best available for primary, I mean, because when things are rolled up and reclassified it may be different for secondary uses that's one comment I have.

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

I mean...

Christina Caraballo, MBA – Senior Healthcare Strategist – Get Real Health

This is Christina...

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

This is David, the only concern I have with my own suggestion is, you know, one man's primary is another man's secondary and vice versa. So...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well...

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

You know the transition is hard sometimes, where do you draw the line?

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well, secondary, do we really know what...I think your idea is right Dave, but from those who led the comments is that what they're talking about? They're talking about uses of the data for research and other purposes, existing clinical data?

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

That was how I understood it.

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

I...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Okay.

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

So, this is Kim, when I hear that I don't think of secondary as strictly being clinical trials I think of it as using it for real world data type scenarios.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

You mean taking regular clinical data and reusing it rather than...

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

Right, right.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Yeah.

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

Yeah.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Yeah.

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

Well, it doesn't...

Christina Caraballo, MBA – Senior Healthcare Strategist – Get Real Health

This is Christina...

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

Typically address anything not governed by HIPAA. I mean, it's Common Rule and other things.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

I don't know what secondary means except I kind of think...I think of it as what Kim says it is data you've already collected, it is as it is and they use it for another purpose or secondary purpose. But, we don't...we could spend too much time arguing about it though.

Christina Caraballo, MBA – Senior Healthcare Strategist – Get Real Health

Yeah, this is Christina, I think it's really important to think outside of the scope of just the EHRs when we're talking about interoperability so that we can also include not just the research companies but also the patient portals and those outside of the certification program that are really going to use that clinical data. So, kind of what Kim said, right, I do think it is important to have that mindset as we continue to build out standards around interoperability.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well, I would have thought portal is already included.

Christina Caraballo, MBA – Senior Healthcare Strategist – Get Real Health

Well, it's not always. So, if you're looking at the most innovative technologies out on the market not all of them are connected to the EHRs so whether it's a portal or other things we don't know about often they're stifled in their innovation because they have no access to the data.

So, thinking outside of our ecosystems of just using like hospitals and those incentivized by Meaningful Use and the certified technologies that are funded to do this then I think we need to shift to being more inclusive and that might be incremental. I know it's kind of a big bite to take but maybe we look at how we can start adding.

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

Well, this is David, I will point out that the big major chunk of the certified EHR requirements for the 2015 edition does in fact concern standards for portal access via APIs, it's probably the single biggest piece of work that the vendors are doing. So, I would say that is already included in the certified EHR use case.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

That's how I thought of it.

Mark Roche, MD, MSMI – Chief Medical Information Officer – Avanti iHealth

This is Mark, I think it needs to include both primary and secondary use, when I read secondary I automatically thought of clinical trials and public health and I think it's good that we're not creating silo'd standards for one specific use that we ensure there is a fluidity of clinical information and reusability basically captured once for use and as many times as possible. So, it needs to have secondary use in perspective and I would agree with that first bullet point.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well, then I think we should define secondary clearly as being the reuse of the same data collected for clinical care because clinical trials often have their own separate collection it's not the same necessarily.

Mark Roche, MD, MSMI – Chief Medical Information Officer – Avanti iHealth

Yeah, they have the separate collection because typically they're either disconnected...between the clinical research and the clinical community is that they don't necessarily come together and discuss how the...information flows more efficient but they sometimes often work in silos. So, this is a good opportunity to bridge that silo.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well...

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

Well...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

I still think we should define secondary to be what we mean, because I'm not sure everybody thinks the same way.

Mark Roche, MD, MSMI – Chief Medical Information Officer – Avanti iHealth

I agree, we can define it.

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

But, I'll also, this is David again, I'll point out, you know, CDISC, the primary standard for secondary use is already in the ISA and the fact that...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

It's not...

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

CDISC is incompatible is not solved by merely being in the ISA. In other words, the ISA doesn't solve problems it is just a list of things.

Mark Roche, MD, MSMI – Chief Medical Information Officer – Avanti iHealth

Right, I think that's good, but I think that CDISC does define their own data elements but I think we can...when we get down to the vocabulary sets and code systems that we assign some data elements, I think we can make a good step towards aligning at least the code systems across data elements.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well, I hope so, but just to clarify, I think CDISC is not in the ISA it's in the possible future, right? If I read it right. So, it's not quite been in the fold. And the other thing is that CDISC just threw everything in, like with HL7 throwing all of the 55 standards in. So, it didn't do as much sorting out as the...

Michael A. Ibara, Pharm.D. – Private Consultant – Michael Ibara, LLC

This is Michael Ibara, there is probably some clarification of this once we talk about what is best use, for example, some of the CDISC standards are there because they've been specified by FDA to be used to submit data. So, if you're using data from secondary use and you collect it from the EHR then you're going to use a certain standard to submit it to FDA. So, I think it's less about we probably can't define...we can probably make more progress if we define, you know, best use and then that solves some of other questions.

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

But it's...this is David again; it all comes back to the use case. So, this has to be use case-based because standards outside of the use case makes no sense, it's irrelevant, that's why we have so many HL7 standards that have never been used.

So, you have to list the use cases and the question then I think becomes what's the breadth of the use cases that we're going to list, are we going to limit it to focus on clinical care or are we going to broaden it to include the secondary uses and I don't care which way but I just think you probably ought to clarify which one you're going to do and identify the separate sections so people understand why there may be some odd transitions because they're not aligned and the ISA isn't going to make them be aligned it's just going to list what people are doing or what people could do, they're really all just candidate standards for most of them.

So, I like the notion of at least clarifying the use case broadly is this primary use or secondary use, is this administrative, you know, knowing that some of these will blur distinctions than at least people could understand why they're reading certain use cases and you probably should list the use cases that you're not considering like I don't know none of the genomics standards for deep genome descriptions are listed here and that's probably appropriate, it's probably not valid material for an ONC funded ISA.

So, I would just make the notion then that we believe that it is appropriate to clarify or I'm getting a consensus that it's appropriate to clarify the broad categories that the use cases address to be determined how many of those categories should be in here or not.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Okay, so...

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

And David your examples of that were administrative, primary clinical, secondary/research that kind of level of categorization rather than kind of a more detailed use case?

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

Yeah, I mean, driven by these two recommendations, you know, on the screen I think those are...that makes sense that people would bring that up. We could probably think of some other ones. I think, you know, it's an open question as to where patient generated data lives. I assume it is part of the clinical use case but we probably want to make that clear.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well, I think given we've got like weeks to do this, I think we're extraordinarily ambitious.

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

Well, Clem, I'd look at this as...I mean, when we have our discussion about what best available means I'm going to suggest that we consider the phrase candidate standards and then candidate would be defined, I would suggest, probably based on whether they are qualified for being included in future regulatory requirements, in other words A119 requirement that it is an open consensus-based standard so it's candidate standards that address important use cases categorized by these broad categories of clinical secondary use, administrative.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well, there is...

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

And you'll never have a complete list.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

No, no I know and I'm sympathetic to what you're saying, but the reason I worry about the blurriness between research and secondary use of clinically collected data is there is a huge stack of standards from the FDA, I mean, it goes forever and we're going to get dragged into that which shouldn't be part of this I don't think. The CF-22 stuff and keeping everything, you know, there is just a terrific amount of...there's a lot of stuff there and if we...

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

But I think, wouldn't it be okay to list that as a category and just say "not addressed by the ISA" and put a link to the FDA's...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well...

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

Website or something?

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well, maybe we split the, you know, you might say the federally reviewed...the FDA research from secondary uses of regular clinical data if people wanted to, but, yes, I like what you said Dave, so...

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

I mean...

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

This is Brett...

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

Go ahead?

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

I was just going to jump in and say, we kind of went down a similar path with the Task Force around security standards in the last cycle last year and that group elected rather than to kind of curate this list of all possible security standards that we should move to add kind of an appendix at the end of the ISA that was a list of kind of authoritative sources for security standards so we could, with your group's consensus and recommendation, you know, move forward to add kind of a listing or kind of a directory of where folks can find that those standards within the ISA, which, you know, makes it something that we don't have to go through and receive comments on and vet when there are other federal agencies or groups that are already keeping those lists very active.

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

I think that's...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

You mean within a given subject matter?

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

Sure, yeah.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Yeah, yeah, I like that.

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

I mean, I like that as a category, however, there is no...none of these standards listed here are usable without deep consideration of the security standards that you wrap around them when you actually use them and the difficulties of interoperability can come as much or more from that as from this standard...these standards that we're considering that are clinical standards or from their vocabularies.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Yeah that's right.

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

So, you can't just say, wave your hand and say, oh, use OAuth that will solve your problem, you have to actually be very concrete and have a particular implementation guide that meets a particular use case and a set of business constraints that the parties agree to abide by, etcetera.

So, you can't ignore that stuff and say, oh, go look at the IETF website and read about OAuth or whatever, pick your security standard, mutual TLS or whatever. This is why this comes back to use cases to me. The use cases pretty much, to be useful, which is what use cases are supposed to be, need to have a comment about the whole stack from top to bottom.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

But...

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

You know using FHIR, FHIR doesn't say a thing about security so you can't say "use FHIR" without also specifying how you do security.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Yeah, Dave, you know, you're absolutely right, but I think we just have to find a way to separate our concerns as you do in everything else to get to closure on anything.

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

Yeah, I think...Clem, my frustration with this approach to listing of standards is that it separates concerns so thoroughly that it becomes somewhat useless. It's the mixing of concerns that yields real world usability, somebody can actually go implement, you know, a particular thing.

So, look at, you know, something like SMART on FHIR, I mean, that's a mix of FHIR, HTML, HTTP, OAuth 2 and then a couple of things that had to be made up. It's not just FHIR or just HTML or just any of those other things without all that mixer thing it's not very useful and that's the frustration to me with just listing standards. This is why we don't have a lot of interoperability is because just listing things doesn't actually solve the business problems. I'm ranting, sorry.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

You've had a hard time, Dave.

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

Yeah, I spent six years...

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

So, I think...

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

Learning this lesson on the Standards Committee.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well, we all have...

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

I have many arrows in my back.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

We'll all have but...

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

Yeah.

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

Well, one of...so, David, one of the things I hear that you're saying and this may could be a recommendation like for...it may not happen in 2017 but as ISA continues to grow is, right now we have this listing but then how do you group them all together to make the magic happen and we don't have the magic yet, right?

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

Yeah.

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

I mean, that's what I heard you say?

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

Yeah, I mean, I think we have it in the real world it's not in this document yet.

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

Okay.

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

And, you know, if you look at the traditional approach was to break down entities into SDOs, which created the standards and then profiling entities which actually mixed standards together and constrained them to solve specific problems, so IHE for example is a profiling entity it's not a standards entity, it doesn't create standards it profiles how to use standards.

So, we've kind of got the analog of that here, the SDO is a list of...I mean, the ISA is a list of SDO products it's not yet a list of profiling entity products like SMART on FHIR or Argonaut, or IHE XDS, or whatever you want to list. Maybe that is something to consider adding is, you know, for each of these standards list known profiles that are in use.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well, Dave, the core of the security problem is the certificate problem, and I don't know if we're there yet, across multiple independent organizations, but that's another story.

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

But most of these profiles deal with that Clem, I mean, they solve that problem one way or another, you know, so look at Direct. Direct solves that with a particular approach using PKI...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

No, no, I know, but...

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

And...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

It's still a big burden and it's not widely...you know there are still barriers and if you don't have...it's still a problem, maybe this end-to-end encryption will be the solution.

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

No, I don't think it will.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Let me see if I can get us back to...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Sorry.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

I think Brett you were asking for feedback on this ISA scope and some of the comments we had received. Are there other categories or comments that we want to try and touch on from the Task Force while we're here?

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

Yeah, certainly if we want to move on we can start to jump into structure comments or I don't know I heard Kim kind of coming up with a possible recommendation that the group might want to endorse before we move on or...

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

I can...if y'all would like, I can take all of these comments and summarize them, and then we can send them out before for people to look at and make comments, and then we can have recommendations at the beginning of the next one to give everybody time to kind of process and think about them, because actually I've been taking notes as we're talking and I have probably a page and a half of notes.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

But, you know, everybody hasn't talked.

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

Well...

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

I hope you're not driving while you're taking notes.

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

No, I'm sitting at a Waffle House. No, yeah, so that's the beauty of kind of summarizing and sending it out it gives people the opportunity like I don't speak a lot on these calls but I like to think about them and put them in writing with everything that I heard so if somebody is like that they can look at them, read them and add the comments in or maybe make a suggestion on the next call, but it's up to y'all, if we want to do the recommendations right now we can do it that way or if y'all want to do a summary from everything we can do it that way, either way is fine with me.

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

Kim and Rich, on one of the previous versions of this slide, in an earlier meeting, I recall there was something about clarifying the use of API-based standards like FHIR which, you know, introduced kind of a new twist to the what I'll call bespoke standard era when you had standards that were purpose specific and now you have APIs that are more generic. Did that get...are we going to come back and revisit that? Because I thought that was another one of these kind of high-level categories that probably should be called out.

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

Was that Rich one of the A, B, C, D like in the groupings for the second phase?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Yeah, I think we have a choice to make here, David, either we can include it in the first tranche that we send to the Standards Committee or we can address it later depending on the time, availability and available to try and get that done. But, yes, for sure it should be included, it's I think a high impact area not only on existing standards but on, you know, kind of how the future is going to evolve. So, what

does the Task Force want to do? Do we want to try and get this into our recommendations for 2017 changes which would mean we would want to try and get it between now and July?

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

Well, let me make...this is David, let me make a more concrete proposal, it won't be a whole lot more concrete, but the thought would be that we would recommend that the ISA should include a section on how to approach API-based standards for interoperability which would include discussions of the things you have to worry about if you're going to start with an API as the basis of your standard instead of a purpose specific standard.

And it would be, you know, just informative, bring people up-to-speed, they would understand that just because you specify FHIR doesn't mean you have done very much that you still have a lot of work to do and so forth. So, that's my proposal is that we at least have something in the ISA that covers that space.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Dave, could you carve out what you really mean? I see that as just a whole universe of everything, an API.

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

Well, yeah, so, we had a...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Not now, I mean...

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

Whole Task Force...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

As part of the...

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

Okay.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

And then that could maybe be shaped into the plan you know?

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

Yeah. We had a whole Task Force on it that Arien and I ran and I'd be happy to send you our recommendations.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well, I heard that and it didn't give me such immediate...I didn't get such clarity on that either.

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

Okay, well, I'd be happy to talk to you off line any time.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

I mean, APIs are used in everything everywhere. So, it's...

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

Right, but, so let me...since you wanted to, you know, bring it up, just the notion of using an API as an interoperability standard is a non-sequitur. APIs are insufficiently specified to be...determined to be an interoperability standard, you must go further and describe how you're going to use those APIs, what profiles you support, what the security model is and so forth. It would be a little bit like saying, HTTP is how you build the Internet.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Yeah.

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

Well, sure it's true, but it's inadequate to say that it doesn't help you at all.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Yeah.

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

So, you need more.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Yeah.

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

And I'm just saying, unlike something like, oh, I don't know XDS, which specifies precisely how to use it including the security model and the code values that are allowed and all of that, FHIR doesn't do that and so we need to understand that even though it is a major advance it's not an interoperability standard by and of itself. It's insufficient. It's necessary but not sufficient maybe that's a better way to say it.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

So, I think, that we've found common ground between that idea and the interest of the ONC was in the area of, you know, APIs related to common clinical dataset, what is contemplated coming up as a result of the, you know, 2015 edition certification standard and not only what it would mean from a perspective for an API developer in that context but also what it might mean to some other existing standards that maybe as a result of that evolution become maybe obsolete by what the future holds and maybe we should be thinking about indications of that, you know, as a part of this as well.

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

Yeah, I mean, that's the spirit, I mean, if you start talking about use of this ISA list for procurement specifications it's a scary thought, you know, the procurement says you must support FHIR, well, what does that mean, there's 120 resources in FHIR and tens of thousands of potential query combinations, most vendors support 10 or 15.

So, we just...the point is, when you're in the API era it's a different set of concerns that you have to wrestle with if you really want interoperability and I'm saying that as a huge believer in FHIR, like don't get me wrong, I love it, but it's not...

Eric Heflin – Chief Technology Officer – Sequoia Project/HIETexas

So, this is...

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

You can't take FHIR and be done.

Eric Heflin – Chief Technology Officer – Sequoia Project/HIETexas

So, this is Eric, I agree with David's last comment, string of comments that...and I've made the same arguments myself which is that an API is indeed necessary but not sufficient and that's actually one of the recommendations I wonder if maybe we can make if we all have consensus on that point which is that the ISA should list applicable APIs and then also list additional known constraints, specifications referencing those APIs as a potential solution for interoperability such as a concrete implementation guide with optionality that's been factored out compare it to the base API upon which it is based as judged by use cases.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well, I've got...you know, as someone who has been doing this stuff for decades, it takes decades and I don't know that we're going to get...I mean, I like what's going on in the API world a lot, but there is nothing really in heavy use. We don't have any experience with them I don't think.

Eric Heflin – Chief Technology Officer – Sequoia Project/HIETexas

Well...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

I think it would be a good thing to put something in but to make it like a specification at this early stage I think is premature. I mean...

Eric Heflin – Chief Technology Officer – Sequoia Project/HIETexas

Well, I would kind of add to that, that, you know, one way of looking at an API is simply it's a contract between a client or consumer of services and the provider of the services, and if you look at it from that kind of a definition then we've had APIs for many years including things like XCPD under IHE or query of transactions under HL7 v2 and any of the things that predates that as well too. The term API is not new...

Christina Caraballo, MBA – Senior Healthcare Strategist – Get Real Health

This is...

Eric Heflin – Chief Technology Officer – Sequoia Project/HIETexas

It's just being used differently now.

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

Well, what's different...what's different is that the APIs of the FHIR era are much more orthogonally designed than the bespoke APIs of the past, number one, they have a cleaner separation of concerns between security and data profiling, which is an improvement, all of those things make them more useful as building blocks but you can't build a building without a blueprint so you've got to have some rules on how to put the building blocks together and the blueprint is actually what makes the building what it is. So, just specifying the API is totally insufficient, I think we all agree on that.

Eric Heflin – Chief Technology Officer – Sequoia Project/HIETexas

I think Clem is saying the...

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

I would argue Clem that there...

Eric Heflin – Chief Technology Officer – Sequoia Project/HIETexas

Same thing here.

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

Yeah, I think Eric you and I are on the same page exactly, I would argue Clem though that there is a lot of work going on with FHIR funded by the vendors and over 60 implementers...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

No...

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

Who are testing it through Argonaut to address the 2015 edition API security or API functional requirements so...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

I also love FHIR.

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

And that work is...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

I'm for FHIR it's just, you know, nothing is in production yet, right?

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

No but that's the point, we're trying to get it to the point of where it can be put in production and then tried out and ONC has telegraphed that if that's successful they'll make it a regulatory requirement after it's been proven in production.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Yeah, well, I think...

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

And I think the ISA...

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

I think someone was trying to make a comment here, I just want to make sure we get everyone's feedback. Was there someone else who was trying to comment?

Christina Caraballo, MBA – Senior Healthcare Strategist – Get Real Health

Yeah, this is Christina, I have two things, I really like Eric's approach with the APIs and defining them a little more. When we hear about FHIR a lot of vendors and providers that aren't in the tangles of what we all do every day think FHIR and they think magic like this is just going to solve all my problems. So taking a step back and making a resource or have the ISA include information on some of the challenges I think could be very helpful. So, I liked Eric's approach on that.

And then going back to what Brett said earlier on the reference list, I think that would be really great. We are...with ISA, remember this is what the third round so it's very new and the goal is to get a living and breathing document where it's a single list for the public to come and look at what standards, and implementation specifics are kind of out there in the pool, so more of a holistic list and this isn't going to be perfect at first but if we can figure out kind of a process to continue to add to it and make it more robust in a way that makes sense now and addresses industry needs then I think it can morph into something extremely valuable and I love Brett's idea of things that we can't get to just putting a list together to say, here's some great resources to solve these use cases.

Christopher J. Hills – Team Lead, Standards Engagement Team – DoD/VA Interagency Program Office

Christina, this is Chris Hills, I would...I'd like to agree with what you're saying, I'm looking at the timeline, we have one month to kind of agree upon this and I do agree that we need to get way beyond from where, you know, I like what Eric and David are saying and I think you're right on to do this, but we need to be pragmatic about our approach and take it from where are and just move it a little bit forward because we don't have time to totally turn this document all the way over and get it to be best of the best of everything and be prescriptive.

And I don't think the industry or the other federal agencies that are using this are looking for it to be prescriptive and to have use cases out the gate. We're looking for this to be industry consensus advisory, what are our options. We have our other documents and other options for getting prescriptive use and how to do stuff.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

I've been reading through the thing, I don't think it's as bad as maybe I was sounding like I thought either, this whole thing as it is now except for some tweaks, some deep tweaks maybe.

Christina Caraballo, MBA – Senior Healthcare Strategist – Get Real Health

This is Christina again, Chris, I totally hear you and would agree with that. I think where I am now is it would be great to just dive in and stop spinning around what the document is or isn't...

Christopher J. Hills – Team Lead, Standards Engagement Team – DoD/VA Interagency Program Office

Yeah...

Christina Caraballo, MBA – Senior Healthcare Strategist – Get Real Health

And just start working.

Christopher J. Hills – Team Lead, Standards Engagement Team – DoD/VA Interagency Program Office

Agreed, let's get moving on this agenda.

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

It's hard to dive in if you don't know what problem you're trying to solve I think that's why we're spending some time on these higher level things, but let's dive in.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Yeah, so part of the agenda...just to make sure that we're all level set, so part of what ONC has asked us to take a look at is some of those meta-conversations around what is the structure, what is the framing, how are we presenting the information as well as the specifics of in the case of, you know, implications of API, you know, how that should go into the document and so I think to the extent that there seems to be a general embrace to address that to some level, you know, then I think it becomes...if it is up to us it is how far do we want to take that in terms of a specific set of recommendations.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well, we've gotten through...

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

So...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

One of the four comment slides and we're now 2/3 over so I'm just worried about the time.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Yeah, any more comments on this one before we move to the next comment slide? Okay, why don't we go ahead Brett?

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

All right, so moving into the ISA structure here, so a comment here about where there have identified gaps in available standards or specifications for specific interoperability needs or use cases, a recommendation to list those in a separate section to kind of highlight where further focus or more work would be required or recognize projects that might be in progress that are working to fill that gap but, you know, may not currently be a standard but that's kind of something in the works.

This is an interesting one where you're adding a category for a ballot in development and creating a section for emerging standards that stakeholders could look to or initiatives that they may want to be aware of if not join. It could be a summary of some of the entries that are part of ONC's interoperability proving ground.

Susan Matney, PhD, RNC-OB, FAAN – Senior Medical Informaticist – Intermountain Healthcare

Well, this is Susan Matney, I have a question about both of those actually, I know in the industry goals and outcomes are not well structured or defined, or and we don't know how we're going to use terminologies to support them to populate them because we don't know how their structure is defined. Is that something that we would put in and identify as a...it's not a gap everybody is using their own work arounds to do it but they are inconsistent. So, I guess it is a gap.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

It sounds like a gap sort of.

Susan Matney, PhD, RNC-OB, FAAN – Senior Medical Informaticist – Intermountain Healthcare
Yeah.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

But do you have other examples of what the commenters were talking about gaps that are active?

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

Sure, so I know there was one for instance that was an example I don't think it made this high-level summary but I saw one that was around closed loop referrals for example and, you know, there is a number of different projects and a number of different kind of work streams that are happening around that and I think that was one where, you know, you could potentially add an interoperability needs section for, you know, close loop referrals and just...you could list something that was in the works or a few things that were in the works.

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

Well, wouldn't you have to say that the big kerfuffle that we have no interoperability is a gap? In other words, all of the complaints that we keep hearing about, about interoperability, those are gaps.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well...

Susan Matney, PhD, RNC-OB, FAAN – Senior Medical Informaticist – Intermountain Healthcare
Yeah, yeah.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well, the big, yeah, there's...I'd throw in radiology, text reporting with understandable codes just at the test level there is a gap.

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

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

And case reporting with no codes at the test level.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
How about the clipboard, every time you go see the doctor, I would call that a huge gap.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

The registration thing?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Yeah, the fact that you have to...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

There is actually a product...

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Fill out a clipboard at every single doctor's visit or...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Yeah.

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

At every new doctor you go to. I mean, in other words, there is an immense number of gaps in the real world the problem is...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

How about the...

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

So maybe...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Patient identifier.

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

Maybe it's less around gaps and more around work that's existing this kind of pre...before even a ballot is drafted kind of a draft in progress level that kind of work that is existing.

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

I think that...this is David, I think that a category that lists the data, the maturity status of the standard itself could apply to most of these standards and so some of them are still in draft, although some of them are actually in use even in draft state, and some of them are fairly mature and are not in use.

So, there is a maturity of the standards from the point-of-view of the SDOs process itself which probably is a valid category and then there is a use...is it known to be in use, which is a parallel or orthogonal category.

I wouldn't create a separate section for balloted standards, I mean, for pre-balloted standards, just describe that as a status.

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

So, that's already...

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

That's my suggestion.

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

That's already in...that's one of the six...those are both two of the six characteristics that we include about every standard or second the ISA, so if there is...you know maybe we just add, as they are recommending here, a ballot in development so that we can show that there are multiple levels.

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

Yeah, that's exactly what I was trying to say, thanks.

Daniel J. Vreeman, PT, DPT, MSc – Research Scientist – Regenstrief Institute

This is Dan, I think that's the best way structurally to handle it. I don't know if there is a lot of value in putting a lot of time and effort into characterizing and making sure all the currently in development stuff gets listed though, right, meaning the purpose of the ISA I don't think should be a list, a bunch of primordial things happening. I'd focus on the things that have at least, you know, passed through the SDO's perspective process.

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

Well, I mean, would you put FHIR in the category of not worthy of being listed or would you...because it hasn't had a formal ballot yet?

Daniel J. Vreeman, PT, DPT, MSc – Research Scientist – Regenstrief Institute

Well, there is...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

It has been balloted actually.

Daniel J. Vreeman, PT, DPT, MSc – Research Scientist – Regenstrief Institute

Yeah, it's on DSTU.

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

Well, that's...

Daniel J. Vreeman, PT, DPT, MSc – Research Scientist – Regenstrief Institute

So, DSTU is a formal, you know, outcome of the standardization process, so I think that fits the category. I think the listing of project scope statements in HL7 doesn't fit the category of stuff worthy to be listed on the ISA.

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

Okay, I will agree with that it doesn't have to be normative is all I'm saying, DSTU or...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

People could...

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

DTU is fine.

Daniel J. Vreeman, PT, DPT, MSc – Research Scientist – Regenstrief Institute

Yeah, exactly.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

And people can go to HL7 to find all those, you know, the speculative new things too or to the other standards groups.

But, you know, I've been...I shouldn't rant, but I have my own rant, you know, for like 20 years labs have been...hospitals have been sending radiology reports around internally and they've been sending EKGs around internally with structure in them, we still haven't even talked about it in the ONC process, biometry is the same thing.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Clem are you making a recommendation on some priority gap areas to be addressed?

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well, it's a semi-gap, all they really have to do is to say, use the lab message and throw in the, you know, normative codes not for the whole texts, we know we're not going to get there for a while, but at least for the names of the darn thing.

And EKGs all have codes in them and Medtronic, not Medtronic anymore, I mean, the company that does them, GE does like 80% of the market and they have a great HL7 output for it we just don't talk about it like it's not important.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

I'm not sure if I'm...is there something actionable you want to see here in the ISA?

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Yeah, to get a v2 message that's got some codes in it for the other tests besides lab tests biometry, you know, there are a lot of codes actually cooking around those both through IEEE and connected with LOINC where one could get the stuff out of the instruments and send it and be read and computed on.

Eric Heflin – Chief Technology Officer – Sequoia Project/HIETexas

So, this is Eric Heflin...

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

This is...

Eric Heflin – Chief Technology Officer – Sequoia Project/HIETexas

Going back to the content on the screen, on these four comments received from public comments, my recommendation is we accept these, I think that they are germane, comment number two I think we've already talked about that we're already going to add a category for identifying...and I think the last ISA actually also already did this, identified areas of interest for emerging standards I believe was the term we used with them, I think in bullet three we've already talked about the importance of use cases and the last ISA actually incorporated use case-driven approaches.

So, I think these comments all make sense to me and my only remaining concern is I'm kind of curious as to why bullets two and three are still here because I thought we actually did that in the prior cycle? But other than that I like this.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well, I don't think there was a consensus on the ballots in development ones until they reached some level.

Eric Heflin – Chief Technology Officer – Sequoia Project/HIETexas

And I'm not sure what we mean about consensus in this case, because I believe the item here would be operationalized in terms of listing those standards that we as Task Force members think are emerging and of interest and should be monitored right.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Okay, okay.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

So with that in mind...

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

So...

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Go onto the next chart Brett?

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

Yes, so this is around...these are comments around the six characteristics, so a few comments that we received here, the concept that production versus pilot for implementation maturity of a standard or spec is too coarse so there might need to be kind of some additional levels there that the group might consider.

The second one here is more around a technical correction where currently under standards process maturity we have final and DSTU the change to move it to STU just based on the nomenclature change there.

The third one is pretty interesting though might be fairly difficult just frankly to include and make sure it is accurate, but including actual cost data in the cost field but a commenter thought that would be extremely helpful to implementers as they are evaluating their standards. I think here...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Can you...

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

Yes?

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Where they talking about the cost to buy the standard or the cost to implement them?

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

I think this was, well the third characteristic as we've created it here on the ONC side of things was around whether a standard has some kind of licensing fee or a charge to use it.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Okay.

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

So, we didn't try to attempt to say, you know, is it free or resource intensive to implement it but whether or not there is a cost.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Yeah.

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

A fee...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Yeah, I take back what I said, I get it.

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

All right, so moving on the next one here is around the concept for consumer use cases and mobile and as we're developing or trying to populate for interoperability needs and standards there the thought that kind of the adoption maturity for mobile and consumer settings might be different so characteristics might need to be addressed as we move into that space and that's probably very true around APIs as well which the group has already been discussing.

Another concept here, which is whether or not there is some sort of qualifier or characteristic that would show whether or not the standard or the interoperability need is accounted for or included in a different certification program, you know, whether or not Surescripts or specific state certifications, or, you know, ConCert by HIMSS was another one that was given here, there is a recommendation that we've heard a few times to add kind of who the owning SDO for a standard is and then a couple of points here on adoption level that I called out.

Someone mentioned there needs to be more detail to ascertain whether, you know, a standard is used in production versus a large number of pilots because, you know, just seeing pilot for one of them might be very different if there are hundreds of pilots versus just one.

And also, we've heard this a few times now, a recommendation to show a slope of the adoption curve to kind of give a sense for whether this use is increasing, decreasing or that something else might be taking its place.

We've heard recommendations around more transparency and kind of what ONC is using for adoption and organizations that maybe even talked to as well as whether it is has been kind of...whether that means it has been adopted by developers or adopted and is in use by providers.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well, I'd like to talk about both the production and adoption are the ones that I think are the most irregular in the spec, you know, you'll see some things that you know aren't very well adopted and then they say they are, you know, big 4 point or 5 point score and other ones the opposite. And I don't know how you...if you have any outside documents say how you rank them or how you decided it to make it more anchored.

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

I mean, what we did on the...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

I...

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

When Dixie Baker's Task Force addressed this question of standards maturity we just ranked them and then we previewed the rankings with the Standards Committee as a whole and corrected with the feedback that we got, it's just judgement calls in many cases.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well, I mean, but, I mean...sometimes you'll see underneath an adoption means more than two it gets one bubble, more than 10 gets three bubbles, more than 50 gets, you know, something like...was there any of that behind it? Because there is a thing that says that the HPI is not adopted by providers, which has got to be crazy in one of the specs, the NPI, the National Provider Identifier, I think, I mean, it's just sort of like a mistype.

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

Yeah, I think the concern here is with...what they were probably reacting to is that the NPI or NPPES number is not used in provider directory capabilities it's used for other...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well...

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

Business purposes but not for interoperability in ONC's sphere and it isn't, you know, it's not used anywhere.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well, I mean, every doctor has to use it, it goes into all pharmacy systems, it goes into all kinds of systems so I don't know...

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

Yeah.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

I don't understand.

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

Yeah. It's not used in Direct or any of the query tools. I think the things that ONC has been focused on are why that got voted that way. But, I agree, these are why you come back to this notion of use case because you might have a standard that is widely used for one use case, is being proposed for a new use case but has never been proven in the new use case.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

I think...

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

It's hard to be generic.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

There are like 10 or 20 that I think we're at least...that doesn't come across right and I'll send in stuff about it. I mean and maybe others can concur or disagree. That I think is what gives me the most shakiness about it. It just seems things that just don't compute and it's being published as sort of a gospel thing by the government.

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

But Clem if I can put words in your mouth, you're not saying that we shouldn't try to categorize the standards.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

No, no.

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

We just need to do...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

I just think...

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

We need to...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

I think if we tweak it a little bit or maybe have a little sentence of, you know, caveat or some, you know, qualifier...

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

Yeah.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

That would explain it.

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

Yeah, yeah.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

It would be more believable and, you know, that's all.

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

Yeah, well it...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Because...mature, they're not bad, I mean, it's not...most of the stuff sort of fits what I think is true but not all of it and some are just whacko now and then, it looks whacko anyway.

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

Well, from a structural point-of-view maybe the attempt to try to put them into hard categories is where the mistake is, maybe it should just be a descriptive field and you describe what...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well...

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

What's available...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Yeah.

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

What you know and then that shows the limits of what you know.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well in some places it is very honest, it says we don't know and then there will be discussions that says, we don't know anything about it, I like that, but...

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

Or you could...on your NPPES question or NPI you could say, you know, every provider that has the following type of degrees has one of these, however, it has not been used for directory lookups despite many requests to be so. I mean, you can be concrete about where it works and where it doesn't work.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Yeah, yeah, yeah. Well, I thought the misunderstanding was there was a discussion in our earlier committees about whether people in the practice who are not billing providers were using it and I think it's probably true they are not but that's not what the words said, it said provider, you know, it said...

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

Yeah.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

It used the words that sounded like the regular providers but...

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

I'm going off memory so I may be wrong, but what I remember is they were trying to use it for role defining for all the members of the care team so that as you got messages back from that person you would know what role they played in their patient's care.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Oh, yeah, no that's exactly right and there was a lot of discussion about whether they are allowed to get them and they are so I think we solved that. But, this...the way this is couched it's not...it may have been influenced by a discussion and confused by it but it doesn't speak to it very specifically, it just says it's not used much.

Eric Heflin – Chief Technology Officer – Sequoia Project/HIETexas

So, back to...this is Eric, back to the prior comment about showing pilot versus production and also the interoperability proving ground being linked to from ISA perhaps it would make sense to combine those concepts along with the other concept of having more structure in the interoperability proving ground to include when submitters submit a statement about the use of a standard in the interoperability proving ground to ask them to also include information we can capture as far as metrics about production use, their view, of the maturity of the standards, their use cases, etcetera.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

That would be good.

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

I like that too.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

And the...

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

I think...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Who owns it, there are websites on the page, so I don't know if you need to add that, but, I'm sorry Dave.

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

No, I was just saying to Eric's comment that the proving ground is a good place for real world discussions about some of these standards and linking them to this document or merging them into one entity makes a lot of sense to me because that's what you want to know is who is actually using it and what is their experience, and how can I get in touch with them so I can ask them questions about how I can use it.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Yeah, yeah.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Okay, any other comments on the six characteristics? Comments on the comments?

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well, I think, I mean, I think at least the statements, the dimensions I think are good and are just...and I already said what I said about the accuracy of them.

Eric Heflin – Chief Technology Officer – Sequoia Project/HIETexas

So, one...this is Eric, one additional thing I think is kind of missing from this list is some organizations specifically focus on these characteristics, it seems like there should be a way to leverage that assessment.

For example, the...I think HL7, which I'm not as intimately involved, has ways where they assess when something is ready to go into a final standard or a candidate for a final standard. IHE, of which I'm fairly heavily involved, actually has an evaluation matrix which is publically posted including additional characteristics such as is it known to be vendor neutral, has it been deployed in production, has it been tested through appropriate, in this case IHE, but it could be genericized through appropriate testing events and so on.

I wonder if maybe we could also take these characteristics and add to that one way of realizing these comments is to include references to standards bodies and others that we are aware of and their assessments of these standards as well.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well, they might be prejudiced.

Eric Heflin – Chief Technology Officer – Sequoia Project/HIETexas

Perhaps...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

I'll bet...

Eric Heflin – Chief Technology Officer – Sequoia Project/HIETexas

But at least it would provide a data point so we can have a link from, you know, pointing to the curator of that standards opinion about its characteristics.

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

Yeah, this is David, I agree with that. I think that was the basis of an earlier conversation we had where the notion that this ISA should be much more of an actively curated document that evolves and captures the current activity in the field which changes literally, you know, from month to month and could include controversy because some of these decisions are difficult.

And that's another reason why best available isn't the right moniker, if we ship it to be, you know, candidate standards or something like that that's a broader range where you could capture some of the tensions that exist when people are still trying to figure out the best way to solve a problem.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

You know...

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

I mean, that's why we have a...that's why we have a Standards Committee right? I mean, there is statutory requirement in law that we have this FACA that figures these complex things out. To pretend that there is no complexity there doesn't make any sense.

Daniel J. Vreeman, PT, DPT, MSc – Research Scientist – Regenstrief Institute

The general idea of linking...

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

Focus on the...

Daniel J. Vreeman, PT, DPT, MSc – Research Scientist – Regenstrief Institute

Linking a maturity assessment to any known sort of published criteria or evaluation I think is a good one. So, I'd support that.

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

Who was that speaking?

Daniel J. Vreeman, PT, DPT, MSc – Research Scientist – Regenstrief Institute

That was Dan Vreeman, sorry.

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

Okay, thanks, Dan.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Okay, great, any other comments on these six characteristics?

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well, I want to come back to one last one, we have an interoperability need, electronic transmission of reportable lab...to public health agencies, we don't have one that says, transmission of ordered test results to providers, that's maybe one...maybe it says better what I was trying to say earlier.

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

So, that's a use case not a category, right?

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

It's a category for public health on page 37, I thought if we had a category we might get some attention to it. It may be a use case too, Dave, I'm sorry.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

We've got that, Brett, do you want to take us through one more page?

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

Just given the timing...

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

Hey, Rich...

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

And...

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

That's what I was going to mention if we should do that one on the next call.

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

Yeah, especially since we were going to kind of start that next call talking about that best available or whatever we end up deciding to move forward whether that's a new term or whatnot, but what characteristics kind of go into something that would be considered a standard that is best available or whatever the terminology is.

So, just as an update from the ONC side of things we are getting closer to being able to provide the full kind of that Excel spreadsheet list of comments that I had mentioned earlier on the call. So, we will be getting that out to the group sometime this week in advance of our discussion on the next call.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Yeah, because some of the broad subjects you mentioned in the previous, I think it was two calls ago, didn't come up in this more detailed comments section.

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

Well, remind me Clem what that is...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well, one of them was...

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

And I can go back...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

One of them was what I think was actually...because I think I know who gave it, it might have been a little bit misinterpreted, about name value pairs is how it was...I think how it came out as the code word on it.

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

Oh.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

With questions and answers.

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

That, Rich, correct me, and Brett, correct me if I'm wrong, but that's in the Phase 2 Section those?

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

Yes.

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

Yeah, okay.

Daniel J. Vreeman, PT, DPT, MSc – Research Scientist – Regenstrief Institute

Okay, as long as it's on the list, I had imagined it as sort of a structural element of how the ISA was set up, but it doesn't really matter I think as long as we get to that discussion.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Yeah, look if the Task Force thinks it's important to address in 2017 changes then we want to try and address it between now and July. If it's where we want to identify things for future addition and put them out there for input then that would be the post July work of the Task Force. So, it is okay to move some of those things forward if you view them as higher priority.

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

And certainly just a reminder if there are topics like this or others that, you know, a subsection of the Task Force wants to take on kind of off line and bring back to us in subsequent meetings that might save us kind of some of the level setting conversations that often take up a lot of time and we can dig right into kind of what the meat of the recommendations are.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Well, I think that's a thing...that space I think could be useful and it is structural.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Okay, so, Kim I think I heard you volunteer to try and pull together a recap of the feedback we got from the Task Force basically a refinement and clarification of recommendations that would, you know, for the Task Force to consider, we'll get that out to you before the next call.

And then what do we want to do at this point? Do we want to go to public comment or are there other kinds of things you want to do in recap before we go there? Hearing none, Michelle do you think...

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

Well...

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

Yes, let's go to public comment, thank you, Rich. Lonnie, can you please open the lines?

Public Comment

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 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

While we wait to see if there is anyone on the phone we did receive some substantial comments from a few folks over the chat and so we'll send that out to the Task Force after today's call.

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

While we're waiting, Rich and/or Kim I'm a little bit confused about what our deliverable back to you is so maybe a summary of what you'd like to get back from us in feedback before the next meeting? What's our homework?

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

Well, one of the things that came up was...can y'all hear me?

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

Yes.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Yes.

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

Okay, was what we talked about with the May 31st like if there were specific things in the ISA document that felt need to be addressed. Clem I think you had a couple of them with the value sets and the pairings and the structural changes and then also with how they are labeled from pilot to production, I don't remember the exact verbiage, I have it in my notes though, like if there is anything in the document that you feel we need to address that may not fit in some of this higher level discussion then please get back to us by the 31st so that we can incorporate that in for the final comments in the first phase.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Yeah, well, actually I just noticed something in the document, I thought CDISC was in a section called "future possible standards" but I no longer see that am I misreading or misremembering? It looks like it is part of the base ones.

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

In that projected addition section which looks very similar to the base ISA but it is...

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Oh, I see it.

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

It is a separate area.

Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine

Okay, yeah, yeah, all right, yeah, thanks.

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

We can go back to that, but we have...

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

Rich did you have...

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

No public comment just so you all know.

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

Okay. Rich was there anything to add of what I just stated for...and we can definitely put together like some of our thoughts. I think if we could go off line with some things that would help like Brett suggested if there are categories that may take a little bit of time, get the experts together, have them come up with a summary conclusion and recommendations to bring that back to the group for discussion I think those things would be helpful too. So, any ideas around those areas I think would be really helpful for the group. Rich?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Kim, I think that was a good summary. I mean, it just...we'll get back to you in writing David, but, you know, just think about the charge that we've been given basically, you know, structure in the ISA itself as well as, you know, additional areas for improvement that we want to see in 2017 and we are looking to jump start some of the Task Force recommendations on that some of which we've started here today, we'll be moving into the, you know, best available conversation next week and then beyond that moving into comments from the community for the next couple of sessions after that.

So, we can...we have some flexibility to bring in additional feedback from the Task Force into that agenda and we just want to make sure that we're getting all of your input as we begin to, you know, take this conversation that we've had today and try and craft it into a set of what we think we heard as possible recommendations. You all have an opportunity to take a look at that and give us feedback on that.

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

Thanks.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Great and finishing more or less on time here. Anything, any wrap up comments Kim?

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

I'm good, thank you.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Okay, Michelle I'll turn it back to you I guess.

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

Well, thank you Rich and thank you everyone for all of your feedback today and we'll be back with you all soon. So, thank you and have a great rest of your day.

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

Thank you.

Brett Andriesen – Project Officer – Office of the National Coordinator for Health Information Technology

Thanks, all.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Thanks.

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

Bye-bye.

Eric Heflin – Chief Technology Officer – Sequoia Project/HIETexas

Bye everybody.

Susan Matney, PhD, RNC-OB, FAAN – Senior Medical Informaticist – Intermountain Healthcare

Bye-bye.

Christina Caraballo, MBA – Senior Healthcare Strategist – Get Real Health

Bye.

Public Comments received during the meeting:

1. Vojtech Huser, MD, PhD; Organization: NLM/NIH: I have structural input to the ISA: The overview of standards is very valuable. Especially the hyperlinks for each standard. To better point to emerging (recent) nature of some listed standards and to complement the maturity and adoption columns, it would be useful to include the following additional data for each standard (see below). For each standard, provide (1) what is the current version of the standard and date of release of that version (2) release date of previous version and what is the type of change from previous version (major additions, minor update) (3) year of inception of the standard (as indication of how old is the standard (e.g., 2014 vs. 1997 provides good indication of when it originated)e.g., CDISC ODM v.1.3.2; released: 2013-12-01 (minor update); (previous version 1.3.1 ; released 2010-02-11); standard inception year: 1997)
2. Jorge Ferrer: Is this the FHIR referenced on the call?
http://www.healthintersections.com.au/?p=2514&utm_source=twitterfeed&utm_medium=twitter
3. Jorge Ferrer: The group should review the consolidated health informatics work on standards.
<http://georgewbush-whitehouse.archives.gov/omb/egov/c-3-6-chi.html>