



Health IT Standards Committee

2017 Interoperability Standards Advisory Task Force

Final Transcript

July 19, 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 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.

Hey 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 is on vacation. Christina Caraballo?

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

Hi, Michelle, I'm here.

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

Hi, Christina. Chris 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, Chris. Clem McDonald? Dale Nordenberg? Dan Vreeman?

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

Here.

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

Hi, Dan. David McCallie? Eric Heflin? Kin Wah Fung?

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

I am here.

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

Hi, Kin Wah. Mark Roche? Michael Buck? Michael Ibara?

Michael A. Ibara, PharmD – Private Consultant – Michael Ibara, LLC

Here.

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

Hi, Michael. Robert Irwin? Russ Leftwich? Susan Matney? Tone Southerland? And from ONC we have Brett Andriesen and Nona Hall; is anyone else from ONC on the line? And have any additional members joined us? Okay, well with that I'll turn it over to you, Kim.

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

Thanks Michelle and thanks everybody for joining today. I think everybody knows we have not a lot of time and a good amount to get through so I'm going to keep my words short and today our plan is to...we had two sub-workgroups that went off and put some stuff together for us, and we're going to get feedback from them. The first one is the structure and vocabulary group and then the second one is the research group; so we're going to go through those two topics today and then hopefully we can finish off Section I today.

So Brett, I think it would be good just to go ahead and move on, unless there are any questions or comments. We got through immunizations on our last call in Section I, which I believe is on slide...

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

Section I-H, yeah, so we were going to start on I-I, industry and occupation.

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

...so we'll pick up on the immunizations after the two workgroup subgroups give their summaries and recommendations. So Dan, I'm going to hand it over to you and if we could get the slides together for Dan.

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

Great, thanks. So this is Dan Vreeman and I'm going to give an update on the output of the subgroups meeting back in June. You see the set of participants there; we had a good discussion and tried to crystalize that discussion into a couple of specific recommendations, as well as one or two just sort of topics I wan...I'm going to mention that we discussed at some length but didn't come to a formal proposal or recommendation on.

So, if you could go to the next slide, this kind of lays out the high level recommendations, and I'll just mention these now as an overview and then we'll go through each one in more detail. So the first one is to...for...so, as a recap, the structure group was focused on issues related to the organization and format

of the ISA and less about the specific content of any particular standard recommendation or the metadata about it, more just about how it was constructed and organized. And so one of the primary things that we discussed at length was the need to use a consistent format that separates the standards for vocabularies and code sets for observations from those that are named for observation values. And we'll come back to what all that means in more detail; we've discussed it on previous calls.

We did spend some time talking specifically about smoking status as one of the sections or the interoperability needs in the ISA that number one, needs to use this kind of pattern or this particular format. But then also has some other specific kinds of issues about it that we'll cover including specific guidance about the use of the SNOMED codes that are in the value sets and recognizing other clinically important variables beyond just that SNOMED CT value set that are important for characterizing and reporting on smoking.

The second top level recommendation was for the ISA to make a visual distinction between the core standards and projected additions. And we have some sort of simple recommendations about how we can make the ISA a little bit more clear to readers, when we're talking about which ones.

The third top level recommendation is to include reference annotations and links to any available public sources that are associated with the adoption level classifications. In past task force calls we've talked about this in various ways but structurally the recommendation is to be sure that those annotations are actually included in the document itself with links to where those can be found. Similarly the ISA should include reference annotations and links that are associated with test tool availability, to make it easier for users who are looking at a particular standard to find out where those test tools are.

And then the two topics I mentioned that we discussed but didn't come up with any particular or specific recommendation was the fact that there were core standards recognized that had varying levels of maturity, as well as projected additions that had varying levels of maturity and how those sometimes can be confused. That is sometimes it's assumed that the core standards are very mature or that the projected additions were very immature or early, but we got some clarification from ONC about that a little bit and didn't come up with any particular adjustment needed.

The second thing that we talked about was this general pattern that applies across both vocabularies and other kinds of standards named in the ISA, which is that often there is a base standard and then on top of that, more constrained profiles or even specific value sets in the case of vocabularies, but other kinds of additional specifications. So there's a general theme that is sometimes there's a core standard and then sometimes there's a more implementation specific thing layered on top of that which could be named. But again, we didn't come up with a specific recommendation about how the ISA should change related to that point.

So if we could go to the next slide, I'll start walking through the individual recommendations in more detail. So first one was the recommendation around observations and observation values, otherwise known as sort of the name value pair paradigm for recording health data, which is persistent prevalence and common across many, many kinds of health data.

So the recommendation is to use a consistent format across all the vocabulary standards names that separates out the vocabulary standard that's being named for observations from the vocabulary standard that's being named for observation values. We thought it was easiest and best to keep both of

those vocabulary recommendations kind of in the same space, tied to a single overarching interoperability need; meaning, rather than create separate needs for the question from the answer, or the observation from the observation value, just keep it organized under the same single interoperability need, but just make clear which standard you're naming for which purpose. And that this pattern or format should be applied both to the main vocabulary recommendations as well as the vocabularies named in applicable value sets as well.

So in the next slide, gives some discussion around this point, sort of backup or background information. So first of all, this general approach is consistent with previous public comments, previous Standards Committee recommendations and also the Regenstrief/IHTSDO agreement on using LOINC and SNOMED-CT together. So it follows that pattern and is consistent with all those previously adopted approaches.

It also was worth mentioning that in some cases, observation values are not drawn from a particular code system, an enumerated list like SNOMED, but rather that a syntax is actually the better way to represent those observation values. So a syntax like HGVS for naming genome variations or ISCN in cytogenetic reporting. And this does...this just sort of illustrates the point that we aren't always talking about an enumerated code list as an observation value, but sometimes we sort of name a style or a syntax that represents how answers are constructed rather than an enumerated list of codes.

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

So Dan, this is Susan Matney; are yo...do you have a slide to talk...this kind of is going along with this slide right here to talk about validated instruments like Braden and Glasgow and things like that?

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

We don't have specific points about those...

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

Okay.

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

...so we were...and I think if perhaps you're going to the point that there are some domains and some variables where the set of allowed answers is quite fixed as opposed to those where the allowed answers could be drawn sort of freely from a broader space. Is that where you're going?

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

Yeah, and I want to comment on that because you know when I talk to like Jan Morse for the Morse Fall Scale and Barbara Braden for the Braden Scale to get it in LOINC, because it's a validated instrument, we don't want them to try and find the answers in SNOMED, we want them to use the LOINC answers.

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

Uh huh.

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

So that's the only cases where I think we should recommend in the Interoperability Standards Advisory that for validated instruments, they use LOINC answers for the answers and not SNOMED-CT.

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

Okay, that's helpful and I think we should try to work in a comment somewhere in this section around that point. Sorry, I'm just making a quick note here.

The other discussion area that we had on this regard is that...just the point of recognizing that some domains or some content areas there's...traditionally medical record systems would have a table structure that holds certain elements, so for example there's a table of allergies or table of problems. And so traditionally you only sort of need the observation value half of the equation because the structural element defines sort of what goes in it. So there's the table of problems and of course that's where problems go; so you don't need a question code representing problems.

But in other contexts, for example communicating that same kind of information in Consolidated CDA that has a different structure, you might need a name value pair mechanism for representing that same information. So in one case you don't need a question code but in the other case you do; and so where appropriate, it makes sense to name both of them so that you know a user understands okay, if I've got this situation, I need them both together but then that doesn't demand that in all cases both need to be used simultaneously.

So you see this often and the messaging or exchange construct sort of influences how the data is represented, but there are, currently in the ISA there are more cases where only the observation value half is listed at all and there's kind of no mention of the fact that in some cases you would need the question part of that, the observation part of that. So that's just sort of a recognition point there.

And then in the next slide, if you go to that, you can see just sort of a brief mock-up of sort of a simple way to implement such a structure. So here you see the interoperability need of gender identity, sex and sexual orientation, notwithstanding any comments we might make sort of about the name of this particular interoperability need or what have you.

But you notice there are two lines there, and I've added another column, which is basically saying oh, here's...one row is the standard for observations and the second row indicates the standard for observation values and here you see how you can use both LOINC and SNOMED together to represent this information; LOINC representing the observation and SNOMED-CT as the observation values. And then in my shorthand here, if you're looking at the applicable value sets you'll notice how there's also a distinction there between a value set which in this case is actually a single LOINC code, you don't...there's not a collection of codes really needed, it's just a single one. But then you would distinguish that from the collection of SNOMED codes that might represent the observation values.

And so...and this is sort of an easy sort of structural thing and obviously stylistically ONC can sort of do whatever they want, but the idea is to label these as related vocabularies but serving different purposes. And that's the intent of the type distinction there.

So in the next slide, we categorized the collection of vocabulary standards that we think need this model applied. And this was from sort of pre...based on previous comments that I and others may have made as well as some, you know Mark Roche contributed some additional ones here and pointed out to me, which I actually hadn't known that even some of the structures that traditionally kind of have their own table in a medical record, like problems, looking at certain implementation guides in CDA, the pattern

that those were being reported actually did sort of require a repeated observation code at the front end.

So again, depending on the use case, you might not need both ends of that...the dyad but it's helpful to sort of name them both so everybody has them in front of them. And likewise, the projected additions that could use this model include two of the nursing interoperability needs. So I'll pause there, that's sort of the end of the recom...that first recommendation, see if there are any other comments.

Hearing none, we can move on to the smoking status one, which is a sort of specific discussion around this variable or this data element/domain. So we noted that this is an area that should and could use the observation/observation value pattern and currently it only has the collected list of SNOMED-CT values, but there's a particular LOINC code that corresponds with that value set that could be listed as the question part of it or the observation part of it.

But as task...as subgroup members noted, the use of the enumerated SNOMED-CT values is a little bit problematic and the...there's need to develop guidance around how to apply that particular constrained list, given the sort of usual clinical practice and the wide variety of other kinds of variables that are used to characterize smoking and smoking status. So that leads in to kind of the second point which is to recognize that there are other clinically important smoking variables just beyond that particular value set. And that we may need to add additional data elements to capture more granular smoking-related facts in a format that allows accurate interpretations.

And so some of those other kinds of data elements include the tobacco type, the frequency, the amount, you know the time to first smoke in the morning like there's just a whole constellation of other variables that can be used. And the same vocabularies are pretty well suited to represent this. So it's not that we need to invent or create new vocabularies, but recognize that there are other data elements that make sense.

So the discussion around those sub-recommendations include the fact that there's been observed inconsistent interpretation of the existing SNOMED-CT codes you know because there aren't formal explicit definitions around them and there aren't direct mappings from some of the more granular variables to those enumerated SNOMED-CT codes, and so forth. And as I noted earlier, there are lots of other variables that are useful and the core vocabularies have most of them. And to note that there is some work underway already on these fronts that Mark is stimulating and others are stimulating that ONC should be aware of and help kind of agitate and stimulate. But that's the set of recommendations around smoking status.

All right, the next recommendation is around the sort of visual distinction between the core standards and projected additions. And this may...this specific recommendation may change, depending on...or the way that we think ONC could implement this might change depending on how the document itself evolves over time from sort of the PDF version to perhaps a more dynamic, live, web-based version, as we've discussed previously.

But in general the idea is, it's really hard to remember your place when you're 70 pages into a document and there's kind of no...there's no bread crumbs around to tell you, is this particular thing a recommended addition or a core standard. And so two thoughts there, on the next slide we thought it would be a pretty easy fix to just add some breadcrumb navigation along the top, to help us...to help

readers and enthusiasts like ourselves, keep track of where we're at throughout the document. And in addition, as the interoperability needs are presented in the document, just to add you know in whatever format that makes sense. I've illustrated just in square brackets here that you know we're talking about a projected addition and not a core standard or a main standard or whatever you want to call it.

All right, so the next recommendation our group came up with was around reference annotations for the adoption level classification. So we had some discussion around this and we understood and recognized the description that ONC's provided around how they came up with these adoption level classifications.

But underneath that, in some ways the specific sources of information are hidden; that is we couldn't...we don't know because they're not noted but we think that there are cases where there are specific citations or publications around adoption levels that could and should be provided or annotated around that classification. Or even simply just noted to be, you know sort of best guess or you know expert opinion/gestalt, which is fine if that's the case because we know that there aren't lots of quantitative measures of these things around, but simply that whatever information that we can reference or point to that would help readers understand where that bubble came from would be a helpful addition and should kind of become a structural element of how the ISA is constructed.

W

...should be good, I mean...

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

Is there comments or that might be background noise, huh?

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

Yeah, it sounded like background noise.

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

Okay. So the next...we can move on to the next recommendation, we can pause at the end if I'm going too fast here. But the similar recommendation around test tool availability was to include reference annotations and links to publically available resources with an indication of whether the tool is free or fee-based. So we couldn't tell for certain, but it appeared as though all of the sort of categorizations in the current ISA were just a binary yes/no, because it just sort of said test tool availability and it said yes. And that isn't super helpful and it seems like there could and should be cases where there are multiple test tools available and so including citations, annotations or links to all known tools would be a much more useful way to represent that information.

And we had a little bit of discussion around whether the ISA should include commercial tools in this case and our softish recommendation from the group was that we would suggest listing only publically available tools in the main ISA documents. And perhaps an accessory tool or appendix or something could catalog commercially available tools. But it seemed like some prima facie be given to the publically available ones.

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

So Dan, this is Susan again. I just...can anybody else, I've lost the slides, can everybody else see them on the Adobe?

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

I mean I can see them, Susan.

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

Okay, I'll log back on.

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

I've had...sometimes I've had...

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

No, no I'm not; okay. Thank you.

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

Okay, sorry about that. I'd, yeah, I think these were also, I don't know if there are any modifications made but this core set I think was sent also last week, too. So it should be in the e-mails for reference later.

So that, yeah that's I think the closing sets of comments around the recommendations, and then I can move on to just the two areas that we had some discussion around but didn't come up with a particular objective. So on the next slide; we talked about how the ISA kind of has these two main sections of recognized standards, which is the main block and then the projected additions. And in both of those places, the standards that are named are sort of rated and noted to be of varying levels of maturity. We've had a lot of discussion around that and emerging standards and so forth.

We've also had some discussion around recommendations for how to deal with sort of the API-based world versus the document exchange or messaging exchange paradigms and so forth. But one sort of helpful clarification we got from ONC was that the projected addition sections were really for things that emerge kind of between the draft and final ISA that ONC specifically wanted further comment on, but didn't want to just sort of push into the final ISA.

And Brett, you can sort of correct me if I've mis-summarized your intention there, but it is...I had sometimes gotten confused that the projected additions were not just for new interoperability needs, but rather they were kind of this space between the draft and the final and not wanting to wait a whole year to get additional public comments on something you know as appearing in the draft. And so the projected additions section was kind of added to help give visibility to those things, but it didn't inherently mean that a standard that was named there was immature or emerging or, you know in some sort of primordial state; it was more just sort of the timing or sequence of how that got named with respect to the ISA publication timeline.

So does that sound about right, Brett?

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

Brett, you may be on mute.

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

Yes I was just playing the dial to passcode and try to get yourself off mute game. Yeah, that does sound right and a good summary of our conversation and kind of ONC's intent with that...

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

Okay, great. So kind of on that basis, we didn't form any specific recommendation to change that and I think it makes sense that even in emerging or sort of relatively immature standard could appear in either place and that that would be fine.

And then...so the next, the last topic we discussed, if you want to go to the next slide, was this general pattern of having a base standard and then on top of that, naming profiles with additional constraints. And so this pattern appears in a lot of different contexts; so just a couple of examples here, right? So you know for sending any kind of result value, whether it's a laboratory test or an EKG or some other, you know pulmonary function test or whatever, you can use HL7 version whatever, 2.51 as the base standard but then, you know in many contexts you might layer on top of that or want to name a specific implementation guide that further constrains that base standard, such is the case with the electronic lab reporting to public health one.

But that same exact sort of pattern appears for example when we talk about FHIR. So FHIR DSTU2 has a resource for communicating observations, but in some specific contexts you want to create and further constrain that core standard to a profile; that's the sort of, you know FHIR lingo. And there is already an example of a US lab observation profile based on top of the sort of core resource of observation that's in FHIR.

But it also applies to the vocabulary standards as well. So you know you might name in many contexts LOINC as the standard for observations, but in a particular domain or data element or sort of sub-category you might want to refer to a specific constrained list of LOINC codes, a value set. And so if you're talking about how to communicate vital signs, you might want to point to only the subset of LOINC that represents vital signs.

And so we just...we had some discussion just around how this general pattern appears and didn't come up with a specific recommendation on how to implement or further refine the ISA's organization. But you see it all over and it could allow you know, in some ways more naming of base standards that today really are used providently for many kinds of purposes, but which there's not really...there's not a specific implementation guide.

So, you know we've lamented the fact that you know sending radiology reports is kind of nowhere in the national radar of many of the things that are happening, but you know in health information exchange around the world, there are hundreds of millions of radiology reports that are just being shared as plain old HL7 Version 2 messages without any particular constraint on how that's done, and there's you know, understandably some variability. But it doesn't negate the fact that HL7 Version 2 is a pretty good way to get it done for a lot of purposes.

So, anyway, we just...we had a lot of discussion around that but didn't come up with a particular plan of attack around it. But as we noted in previous calls, this pattern does apply, even to the newer things such as API-based standard specifications.

So that finishes kind of our subgroup report and I'll turn it back over to Kim for either further discussion or for us to move on to the other recommendations.

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

Hi, this is Mark, Mark Roche and I had one comment. Can we go to the slide with...regarding the smoking history.

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

Yes.

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

I think we're recommending the recogniti...recognize that other data elements are available to capture the tobacco type. One of the comments that I had is whether we can actually solicit feedback from the community once the Interoperability Standards Advisory draft has been published, to solicit the feedback and ask hey, what are other ways that you currently capture smoking information in your information system?

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

Yeah, I think that's a good addition, Mark. So we could definitely recommend that ONC, I think the way that they're doing that now, they have a little...a link to a particular question about an interoperability need and I think it would be helpful to specifically call out that feedback.

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

Hey...

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

There are actually a number of survey instruments that deal with that, as you probably know Mark, including I think one from the NHANES study and there's one in an NIH group called NCNX and there's a couple of them...I mean what I remember when I was still seeing patients was pack/years, which is the most common way.

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

Right. I guess where I was going with that question is, it would be helpful to understand how the vendors and data base service providers actually capture that information in their own information systems, so that we can get a better understanding of how the data is collected so far, and I think that gives us a better understanding of, you know what to do next in the upcoming years.

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

Yeah and Mark I have an apology that I haven't gotten back to you but I've been working on it and as I've been also trying to get this genetics HL7 V2 Genetics thing together in time for getting it for ballot shape. But if you can be a little more patient, I should be able to get you something.

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

Okay, that's good.

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

This is Kim. So as I've listened...thank you, Dan and the group for putting all this together. So I'm trying to, in my mind like put these in the places where we talked about different things in the document. And just off the top of my head and Dan, tell me if I'm on track or not, so...because I want to be able to capture all the things that you stated. Like with the test tools linked annotation, the breadcrumb piece and the definition of projected addition; like would that fit under like our recommendations for the structure of the ISA document? Like we could probably add in some comments, extend some of the examples to capture that; would you say that would...

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

Yeah, yeah, these were mostly meant to be sort of broad, you know broad statements that apply across kind of the whole document. So I would suggest we kind of frame these recommendations to ONC in that light and I've tried to include some just examples to help you know illustrate the point. But even more probably could be done but yeah, that's I think the idea.

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

Okay.

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

But you know, I mean if I could just put a little couple of points to that. So clearly, you know what the breadcrumbs things can be done with appropriate top of page titling where you say more than one thing and probably wouldn't look like computer breadcrumbs, but it's very common in documents. And then the thing is some of the things about the observations and answers, I think you could target that closely, because there's some of the places where it's divided up already that way and a number of places where it's not; so, you might be able to tie that more specifically in 10 or 20 locations, I think...

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

...Dan kind of aimed at that.

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

So for the observation and observation values, and I'll need to kind of go back and look through the document, but my initial thought was should we have a blurb at the beginning of Section I that defines those concepts and what we recommend for it? And then obviously as we're going through each of the sections, for Section I we would point out this is one that needs an observation and an observation value, right? So we would put them in there that way with like the smoking and the gender identity, we would have a comment that these are ones that we recommend with that. I mean we could have a list, too, but that way it's kind of all in there together.

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

Right. This is Dan, yeah, I think that general approach would make sense to have something at the beginning that kind of defines that context and then as far as our recommendations, I just kind of dumped the list of places where I thought it should go. But I think as we provide more structured

feedback, you know noting that, kind of a section where we say it should apply, you know, I think would be a helpful way to take that feedback.

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

Okay. And then like the smoking recommendations, when we get to that, which hopefully will be on this call, we can incorporate these concepts into that smoking section, is that what you all had envisioned?

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

Yup.

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

Okay. And then the one with the base standards and profiles, I was trying to figure out where that would fit. We had a comment about the profiles in one of our objectives at the beginning, I don't remember exactly where it is now, but I'm wondering in the slide that Rich put together with improving use and function of standards, if some of these examples fit in with that slide?

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

Umm, yeah; I vaguely remember that. I don't know that I had a specific place in mind. We were sort of, you know given that we didn't come up with a particular direction, I'm not sure...or proposal, if some of the discussion could be helpful to other points we're making, I think that's great. But if there's not a natural place to put it, you know I'm okay with leaving it sort of by the wayside.

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

Okay, so in slide...I don't know if you all can jump to slide 71 and Dan could see it real quick. It may not be the right place, I'm just...as you were going through, I was trying to figure out where everything fit into the document and those were the main things that I've noted. Is there anything that I missed?

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

So Kim, this is not really answering your question but going back to the point about the answers...the observations and the values; there are some sections that actually do separate them and so we wouldn't want to, you know besmirch the document where it's done it the right way. That's all I wanted to point out.

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

So maybe our comment at the beginning is we should be consistent.

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

Right.

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

Yeah, I mean it may be not the best format, but there's some there where it really was split out.

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

Right and actually Clem I was sort of proposing that those get shmushed or merged rather and that would, the consistent format would be the merged representation where there's a single need at the top, but then the two vocabularies that you would need would be underneath that single need.

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

I think that would be clearer; that's probably a good idea, yeah.

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

So Dan, this is the slide that I was talking about with the base standard and the profiles. And you can think about it, you don't have to answer right now if you want to look at it, but that was the one I was referring to, and it may fit somewhere else. That was just me like real quick trying to put things in their...into certain places in the document.

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

Uh-huh.

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

So if you want to think about that one and get back with me, that's fine.

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

Yeah these...well the...just at a first glance, these seem like more like you know annotations that would help a user or an implementer make the best use of one of the standards that was already named, whereas the two other kinds of annotations we're talking about, which you know maybe there's like a little you know, annotation section in addition to the section on limitations would be around the test tools and the...any source data or source information that was used to assign the adoption level.

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

Okay.

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

So this is Mark; I have a question on this slide, Argonau...it says the ISA TF recommends that in the interest of improving the use and function of existing standards already in regulations; and then one of the bullet points it says Argonaut Implementation Guide. Is that referring to FHIR?

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

So Mark, this is an older slide with our running recommendations that we presented in the June Standards Committee and Rich put this together so I don't want to make an assumption.

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

Well I think...

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

The reason why I asked that is that FHIR is not an existing standard already in regulation so, I'm trying to understand how a person outside of this committee would read this set of slides and interprets the

Argonaut Implementation Guide in light of the introducing sentence about the existing standards already in regulation.

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

Okay.

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

I think that's a good point Mark. I mean I think it should be parsed out; there may be some Argonaut recommendations that do apply to existing and some that don't. I haven't read them myself. Do we have them?

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

Okay, so I think I may have gotten us off track with what we're trying to do. I was just trying to fit in some of Dan's stuff here, so why don't we go back to the end of Dan's presentation and are there any other comments with his presentation?

Michael A. Ibara, PharmD – Private Consultant – Michael Ibara, LLC

This is Michael Ibara just to say I strongly agree with all these recommendations. I think they would go a long way toward making the report readable and very usable to naïve users. And even getting it, you know helping to clarify questions like we're just discussion, whether something's in regulation or not. But the visual representation is tremendous, I think and the recommendations on adoption level classifications I would say are essential to prevent confusion over how conclusions are gotten to.

Maybe even, I was considering recommending that there be a short statement about methodology and how this stuff was done. As Dan said, whether it's just gestalt, that's fine but just let people know up front and then in particular, these adoption level classifications would help guide them through to understand for each one exactly how things were gotten to, whether there's concrete information or not. But in general, I would strongly support all these recommendations.

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

Okay, thank you. Any other comments? All right. Well thank you Dan and group; Brett and I will work to incorporate these in and now we're going to move, Clem are you ready for the research section read out?

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

Clem, are you still on?

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

Yeah I was, but I was the old mute button. Do you have my...you have the slides?

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

Yeah, we have the slides and just real quick Clem, can you tell us like before you go through the recommendations, because as I went through them, I was trying to figure out where this goes in the ISA document, so that my brain can be on that labeling as I'm listening to it?

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

Well this mostly relates to the new proposed sections that describe research in their headings.

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

Okay, so this is a new proposed section for research.

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

Well, I actually...I'm not sure if it's a new proposed section or whether influences the sections that were...so these weren't sections, these are proposed standards under headings called research.

Michael A. Ibara, PharmD – Private Consultant – Michael Ibara, LLC

It was the protected additions section mostly.

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

Correct, thank you.

Michael A. Ibara, PharmD – Private Consultant – Michael Ibara, LLC

Yup.

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

And so I don't know if this is a section or just makes recommendations about what's in that section; you can judge as we go through it.

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

Okay. All right.

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

I mean maybe there is a little section. So it...we didn't have a thousand people on this task group, by the way; so this is the list of folks who participated. So next slide. So this just to reiterate, our charge came from a previous meeting, I think on September...on June 22, I think it was, and it was the 2016 ISA proposed a number of research-related interoperability needs in the projected addition section. This list needs to be further defined to ensure only relevant and necessary "recognized standards" are listed. And then it said a subgroup was currently working to develop recommendations. And that was us. Next slide.

That might help you Kim, to focus what we're...and then, I just...just a couple of definitions, and there's a lot of them. Medical research is the basic research, applied research or translational research conducted to aid and support the development of knowledge in the field of medicine. It's just sort of a throw-away slide. Next slide.

And then, I just want to be explicit about what I'm going to be talking about, medical record data, but I want to make sure it's thought of broadly enough in our discussion. So what I mean by it is pharmacy

dispensing records, medical order data, payment records that include diagnoses, treatment codes; adverse event records, so anything that's generated in the process of caring for medical care and recorded in ways that we might gather it and use it. Next slide.

And then just a little background, in terms of...the question's what's the tail and which is the dog? So I did...I could find 2012 figures, so the cost for healthcare in 2012 was \$2.7 trillion dollars and the total US research expenses in that year was \$120 billion dollars and it's really 4% of the total care delivery costs. So it's important, I've been a researcher, but it isn't dominant over healthcare, patient care. Next slide.

And this was a recommendation; this is actually a recommendation that's copied from a June 20 meeting of the whole committee, of our whole task group and it says, "the ISA document should focus on data standards...I think Kim, I think you crafted this...focus on data standards and interoperability needs for certified health IT and will, when appropriate include an appendix which references authoritative standards for other standards in healthcare, including security, administrative, research, clinical trial, etcetera." And so this gave us sort of some focus and guidance. And it also said, "secondary data used for ISA purposes will be defined as the reuse of the same data that is collected for clinical care." Next slide.

So the recommendations, we don't want to create barriers between clinical care data and research, at least those that are not necessary, and having different standards could...will hinder research. And we...the strong recommendation, we should follow the guidance of the June 22 HIT meeting and focus only on data standards and interoperability needs through Certified Health IT in the ISA. So we're just kind of saying the same thing that was said at that next meeting...that meeting. Next slide.

And then specific to this projected additions in ISA, Section IV which starts on page 40...53, the HIT committee position stated above has implications that the following specifications should not be included in ISA itself; but some would be candidates for the appendix on research. So I'm labeling these as A through E; on page 57 which is described overall as representing the analytic data for research purposes, and I think they're mostly CDISC standards. Page 61, which is titled Research, submissions of analytic data to FDA for research purposes; this is what we might call regulated research.

Page 62, there's a whole set of standards for pre-population of research case reports from electronic health records. Page 6...and that's mostly HIE, by the way. And Page 63, integrate health care and clinical research data by leveraging, I think it's HE...health in...it's not HER I don't think, it's...I think that's the spellchecker changing health records or something into HER, and other IT systems, while preserving FDAs...I'm sorry that's typed wrong, too...requirements. And there are two sections with the same title on the same page. And then page 65, registering a clinical trial; and this is really a CDISC clinical trial registry. So these are the fi...there's a lot of pages and there's probably 25 or 30 specifications listed; next slide.

And then some of the standards proposed in the above, and I'm describing them from A to E, would be very appropriate for inclusion in an ISA inde...appendix on regulated standards and specifically, to cull out or call attention to the CDISC study data tabulation model, which carries raw data for studies required by...for the...by the FDA for use, and is already used widely. And then the CDISC Define-XML ODM-based study metadata concept. So those I would highlight as two out of the bunch that really should be included.

Some, I know for...they'd be wrong, so the Section E is a registry for clinical trials and US federal law requires US studies to be registered in an existing NLM Clinical Trials.Gov specification. I think this was introduced by CDISC for use by other countries, so I think this would be very confusing to say we should use this other standard instead of the US standard.

And then I would be very cautious about including any of those in Group A, page 57, which recommends the use of CDISC specific vocabularies, which are different from and conflict with federal medical record vocabularies and would obstruct much of the research that is dependent on medical record data; that includes the...all kinds of things that are going now, going on now including precision medicine and the FDA's Mini-Sentinel and there's just lots of research done on existing clinical data and it would not help to get people using two different specifications in those. Next slide.

Now further, the FDA has...is actually launching an effort to unify clinical research data by adopting more of the clinical standards. So through the Centers for Drug Evaluation and Research (CDER) and the Biologic Evaluation Branch (CBER), FDA has decided to adopt logical obs...the LOINC codes as "part of a larger FDA effort to align the use of data standards for clinical research with ongoing nationwide health information technology initiatives." And this is specified in the Federal Register announcement May 14, 2015; I've given the reference to that. So the next slide, if there is one?

Now the specification on 63 and 64 may be....these are things that are ok...not bad, but I think they're already specified in clinical portions of the guides; they're mostly IHE standards or things that will be in FHIR, like the SDC. CDASH does overlap with FHIR capabilities, so would be cautious about promoting it at this time. And...let's see IHE for...and I'd also, some other worries about pushing IHE for the data capture standard when FHIR is so close to providing the capability. But others can decide about that.

So there's one set of these that's mostly not CDISC standards, 63 and 64, but most of them are only mentioned or requ...elsewhere in the document, like HL7 CDA; these are already specified many places. So whoever you know goes through this might be aware...will avoid trying to put them in two different places in the ISA that would just confuse people. Next slide, if we have one more.

I'd also suggest, I mean this I think is mine, not from the committee that in reading over the specifications in this research area, it was very hard to know for many of them what they really were. So I think we should really ask that any new proposals have a two to three line description in sort of lay or medical lay/terms of what it is and how it's used. And so many of the proposed research standards had only an acronym, no descriptions and there's one called SEND, which actually the sixth standard on page 61, which is actually a standard for the raw data in animal study data; it did share it with 9 women, but it wasn't really clear to me until I discussed with experts what these really were. I don't know if others had the same trouble.

And I think this is the last slide, let's see...hit the next one. Is this the end? No, yeah; okay. So that's the...my presentation so other discussions or comments or retractions or changes? All of the above?

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

Clem, this is Kim and I don't know the answer, but how is like PCOR, PCORI, PCORnet fit in to this research section?

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

Well PCORI is all based on routine clinical data, I mean there's two models; one of them is the Mini-Sentinel model and the other one is the I2B2 model and they're both focused on collecting clinical data as it exists in medical record systems. PCORI's goal is to do both comparative effectiveness both...and patient oriented studies both on...both as observational studies, which almost...which all fall back to being walked, you know existing clinical data or as pragmatic are large clinical trials or what do we call them, large, simple clinical trials, which also tend to depend upon existing clinical data.

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

But do we need a statement about that in this section or...

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

Well actually, I had, I think I dropped the slide out, I had a list of proc...things that used clinical data on another slide which fell out, I mean when I was moving them around, I guess and is that what you'd like? I think I listed PCORI and Mini-Sentinel and ODYSSEY and some of these other large observational databases that are just, they're almost totally based on you know existing clinical data of the kind I defined as medical record data up above.

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

Well I'll open it up for the group. I just...

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

This is Christina; I would recommend adding to the medical data slide something on patient-generated health data, a need for standards around how that's captured. I know that is of interest to some people...

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

Oh absolutely, I just want to in fact that that was a big oversight. But I didn't show you the slide I had and I'll produce it after the fact and you can look at it, have them add it in to this, but that's a good point.

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

And Clem, yeah and on that slide with the adverse event records, I guess there's controversy about what that really means in the EHR.

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

Well, I'm not sure what you're referring to. There is something called MedWatch, which is an FDA proposal to...for people, this is clinical people, to report adverse events, and there's a whole bunch of...there are many efforts to standardize adverse event reporting. But the Mini-Sentinel, which is a \$180 million dollar FDA funded project is just a collection of medical records data and insurance company data, and that's also intended to research questions about adverse events; is that what you're talking about? I'm not specifically identi...knowing of a controvers...the controversy you're talking about.

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

Well, with what we were talking about, because it says medical record data, so I'm making an assumption, and maybe that's wrong, that its data that's contained within the EHR...

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

Well, no I broadened it deliberately, but maybe it didn't come across saying pharmacy data, billing data, the things that are generated as the process of healthcare. So that may be too narrow, yeah.

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

Okay.

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

And you know, and there's always edges and gray zones that I don't...it's hard to totally categorize. But mostly what we are talking about is that which is captured and put into a medical record, not all. And in fact, the patient collected data is also put in there routinely. So other comments, I mean this is really sort of a, I mean to be...it is sort of a push to remove some of these many CDISC standards from this research area, at least some of them, ones that collide with routine healthcare standards. And I don't know if that's sensitive or objectionable or...I'd like some discussion how people feel about it.

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

Well Michael Ibara, you were a part of this group and you work at CDISC so do you have any comments?

Michael A. Ibara, PharmD – Private Consultant – Michael Ibara, LLC

This is Michael Ibara; from my side I think Clem's hit on a core issue and a very difficult one. And it really goes back to his first...one of his first slides about the purpose of this document. And if we're trying to focus, as Clem's slide said, I don't remember the exact wording of it, but if we're trying to focus as we were talking about to look at you know healthcare-related, healthcare use-related information, then I think a lot of this flows from it.

But I don't know as a group that we've ever had a discussion about that purpose because it seems like the way to document it is currently with what it contains belies that purpose. So if the group agrees that we're trying to focus down much more specifically on healthcare-related directly and then make research separate from that, then I think all these things flow. But I think the problem is probably we've never discussed that major point to begin with.

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

Well Michael, it was discussed, but maybe...and it was presented in a slide, but maybe it wasn't attended to enough, on June 22.

Michael A. Ibara, PharmD – Private Consultant – Michael Ibara, LLC

Yeah.

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

That first slide was copied verbatim, I didn't write that and...

Michael A. Ibara, PharmD – Private Consultant – Michael Ibara, LLC

No, yeah; exactly, Clem. That's what I'm saying is that when you read that, I think it's very clear; the question is, can the group read that and agree in principle with it, yeah.

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

Right. So we should...I think we have a relatively skimpy group today, right? I mean it's not the full mass; there are voices I'm not hearing.

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

We've actually...people have slowly trickled in; most people are actually on now.

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

Okay, because what this focus wasn't on medical record or healthcare, it was on certified health IT in this particular phrasing. And then it also allowed, it said we should put other stuff that's appropriate in an appendix. And I mean there's a lot of stuff that we haven't touched; X12 is huge in healthcare, I mean in terms of billing and inventory, but we haven't mentioned it because it's not part of this functional part of the H-I...health IT that has been defined in, really in Meaningful Use and all.

So...but what I really worry is that if we introduce a set of standards for vocabulary that are being proposed as broad use and with the research, all research, you know covering the whole span of all research, I think we're going to end up with a lot less standardization and a lot less useful data. And in the regulated area, I think that's a different game and we would and I sorted that out specifically.

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

This is Christina; my understanding was, in our June 22 meeting, that we wanted to focus on the certified EHRs but then...or certified technologies, but have references for those that may not...that are more...that are using the certified technologies, like the research organizations, eventually the mental health and others that will leverage it, but aren't necessarily directly coming and looking at it.

I know just...I've seen an uptake with people referring to my...the ISA within my business development team, coming and just saying hey, does your organization meet this group of standards that the ISA refers to for certain use cases? So I think it is important to keep that in mind so that those that are going to use it outside a certification program, just because they're looking to be interoperable, can reference ISA a little more easily.

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

Well ISA...well, this has a bullet already, not my bullet, secondary data use will be defined as the reuse of the same data and I think, is that what you're talking about, the same data collected for clinical care?

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

Christina, are you...

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

Christine...

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

Yeah.

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

Because I mean nothing you said bothers me, I'm just not sure whether you think we should bring in and wave, now wave the flag or encourage the use of the CDISC vocabulary standards in addition to the clinical standards in the clinical care or even the research using clinical care data.

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

Well with that statement, how I remember it, because the security one is a good example because that was one that we worked on last year, and we put a section that referenced to other places who maintain and update the security standards, much quicker and faster than the ISA document would. So Christina what you're saying is for research, should we have some links to different places that could lead somebody to where they could find more information on research standards?

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

Yeah, I think that would be helpful. I guess I'm thinking that we were going to include some of these use cases in our area on the projected additions.

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

Well I was actually...this statement I used that we wouldn't put them in projection in ISA, we'd put them into an appendix, as with security and maybe things like X12 for the business stuff, but the other...

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

I think that's fine, I think as long as a resource is there.

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

...no the other thing is the way, you know research was for regulated clinical trials done by drug companies, is not all research and it's sort of, there's some confusion there. There's a ton of research that goes on just purely with clinical data, even clinical trials that aren't FDA you know types of trials or after marketing. So I worry a little bit about the research wand pulling all clinical data into the regulated area, which it isn't.

You know I just said, people are going to be using this research all the time for secondary purposes, mental health, you just mentioned Christina, so I...there's two issues here; the label research kind of assumed it was all just one kind of stuff that goes to the FDA, and I thought, that's a problem.

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

Yeah, so in my mind I think of it Clem like clinical trials is what you're talking about with the research.

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

Right, right.

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

And then the other part of it is like real-world data, real-world evidence...

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

Right.

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

...and so that...a lot of that like we have data marts that are straight either from a claims payer, from EHR data that we can go into to get real-world data, real-world evidence on different things, and I don't think we're the only company that they have businesses that provide these, so obviously a lot of people use these.

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.

And so we use them for those purposes, for real-world data evidence and then if we wanted to look at it in the real world, outside of the data mart, it could help give us direction with it.

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

No, I'm a 100% with you, I mean I tried to explain that there's a research world that's much bigger than the clinical trial, FDA-approved research.

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

There's even clinical trials using clinical data only, you know in clinical institutions like after the drugs have been marketed, when people are comparing two drugs in a trial, they'll just be hospital-based or a consortium of hospital-based activities with usually not any major data collection outside of what you could collect otherwise. And PCORI is all that, too and...

Michael A. Ibara, PharmD – Private Consultant – Michael Ibara, LLC

Maybe for...this is Michael; for our purposes it's probably important to distinguish between exactly what you're saying Clem, but more from the side of who's receiving it. For example, there's far more

comparative effect in this research out there, which doesn't go to a regulator, per se and that's still research.

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

(Indiscernible)

Michael A. Ibara, PharmD – Private Consultant – Michael Ibara, LLC

On the other hand, you may use real-world data to be submitted to a regulator, but if it's being submitted to a regulator, then that would come under the auspices of regulated research.

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

Well even that, you know since the FDA is now push...is proposing LOINC should be submitted for lab tests, it isn't necessarily true that it's got to be using CDISC vocabulary standards.

Michael A. Ibara, PharmD – Private Consultant – Michael Ibara, LLC

No, I'm just saying for the distinction between regulated and non-regulated, yeah.

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

No, yeah, yeah, I agree with you. I would agree with you. So...

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

This is Dan. I would just say, in...primarily because of the two factors already outlined; one, the sort of main focus being on the certified EHR, that sort of Health IT space, and two being this not wanting to lump all research into one bucket. I would support the recommendations that the subgroup came up with.

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

I don't think we exp...elucidated that as well as we could have, that split...not of putting them all in one bucket.

Michael A. Ibara, PharmD – Private Consultant – Michael Ibara, LLC

Yeah.

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

Well I mean, that was the in...I inferred that based on the discussion and the references to things like PCORI and Mini-Sentinel and the other observational kinds of data.

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

Oh, I'm sorry, I did lo...I forgot, I didn't talk about...I did include that slide, okay; but I need to add a couple more, Christina's position. I thought I didn't. Well I think, it's on my handout, is it in this set of slides? Did it make it?

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

I'm not...

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

I mean I printed it, it is in there?

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

I don't think it was in this one that we got today.

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

I think it got lost, I mean I'm looking at it from what I thought I sent, printed out and it's the spectrum of medical research. I have clinical trials, regulated pre-marketing for new drug device, non-regulated, non-drug device that is in post-marketing studies; that may not be very clear. Then there's clinical trials non-vendor studies of drugs...large, simple, pragmatic trials which may be randomized; quality assurance studies; observational; comparative effectiveness; outcomes management; PCORI randomized and observational; precision medicine; large database research such as Medicare's chronic disease database and ODYSSEY; post-marketing surveillance such as FDA's Mini-Sentinel.

So that slide, I was afraid got lost somehow between my writing and the sending. So we'll send it to you and we'll add in patient outcome data and patient collected data.

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

Okay. Any other comments?

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

This is Christina; I had one more comment. The...taking out the IHE for the data capture; I'd like to understand that a little bit more. I...it's...I don't know where that slide was, but it was in favor of FHIR.

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

Well I...

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

This is more me talking to my technical team, my solution architect kind of was at me about it saying well why don't we use IHE profiles and stuff that already exists and things we're already using. So based on that conversation, I'd love more feedback and understanding of why we would get rid of that and we don't have to discuss it now, but is it something we want to keep for public comment on that?

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

Well let me clarify because I didn't really mean it that negatively, I just...I thought we just should be...if I'm assuming there's smarter people and bigger forces that are up above and I may...and they, if they, if they're really going to push that we're going FHIR all the way, I mean you get some sense of that; certainly the industry is pushing. We should at least be cautious about pushing something that's still new or brand new versus it.

I wasn't saying we shouldn't adopt it, I mean I wasn't saying to get rid of it, I was saying two things; there's IHE specifications in there that shouldn't have to be separately in the research section because they have multipurpose uses. And there's other standards in there like CDA, HL7 CDA which doesn't have to be singled out for research because it's used everywhere you know, in healthcare and it'll show up anyway as an ISA standard.

So some of the IHE ones I think are going to show up anyway and there's an IHE for radiology reporting, which is really a version 2 in a wrapper and there's a lot of IHE standards that are...that we should be aggressively supporting it was just the SBC one that it just felt we ought to at least be cautious about because it may...might get supplanted by FHIR. And that would be up to people watching the industry better than I.

Michael A. Ibara, PharmD – Private Consultant – Michael Ibara, LLC

This is Mike Ibara; two comments on that. One, I think that probably goes back to when we were talking about, originally when we sort of went round on our methodology and how do we...how does ONC decide what goes in there and so that probably...we could probably answer that if we go back to our earlier discussions and say, is it used now and if so, is there something emerging, rather than trying to anticipate what will emerge, maybe state how it is now.

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

Yeah.

Michael A. Ibara, PharmD – Private Consultant – Michael Ibara, LLC

The second comment is in terms of the...those profiles maybe and for IHE and other standards perhaps going forward in the future, the more we try and merge healthcare and research I guess the more standards may get used in both spots and so maybe we want to consider for the individual standard calling out the fact that it's also used in a certain way. For example, CDA is used in healthcare but also often the basis of some regulated research, maybe we should just make a note that it's used in that way as well.

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

Yeah, that's a good idea. But I'm, you know, if...but I think if we could sort of say that in one place instead of having users struggling to find, you know, it's a pretty big document already, you know seeing it in many places. I don't know how it should be laid out though. So those were just cautions and not strong recommendations on the IHE side. And some of them were really not, I wasn't trying to...I really should have said some of them are there or should be there, but I think they're already there in the upper sections they don't have to be in the new proposed section under regulated research.

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

Okay, any other comments?

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

Well, I mean I'd like a sense of whether the report, maybe it's for the other one, too; is this...can we take it as it's been an accepted report by this group?

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

I've heard people say that they were in favor of accepting them; probably what we'll do is we'll consolidate it a little to fit into our recommendations for the presentation for the Standards Committee.

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.

But the concepts should be there that y'all proposed.

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

I'll get you this missing slide that I read, but I didn't include somehow.

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

Okay. Is that how everybody...is everybody in agreement with that?

Michael A. Ibara, PharmD – Private Consultant – Michael Ibara, LLC

Sounds good to me.

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

Sounds good.

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

Okay. Perfect.

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

Yup.

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

All right, well we just have a few minutes and I think we're on slide 46, so we probably can...or did we do industry and occupation? We probably can get through one and then we'll have to stop for public comment or Michelle, did you want to talk about breaking off for Section II and III? What would be your preference?

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

Brett, what do you think?

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

I mean we could start to go through the industry and occupation slide, we might be able to do it fairly quick, but we do publically want to discuss Section II and III and how we want to cover that at some point before public comment, too. Let's quickly try to do this one; there's not a whole lot here.

So from public comments there wasn't really a recommendation on proposed standards for inclusion but there can be some clinically relevant pieces from industry and occupation; but folks generally felt it wasn't enough to make sure that that was included in the record. There were a few different value sets defined or recommended; those are listed there so we could adopt those. It looks fairly...it looks like there was some agreement among the task force there for some of those value sets to be listed, and then a recommendation to allow some free text rather than to use kind of a look-up tool and a standard there.

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

Hi, this is Mark Roche, just to give you a little bit of a feedback...a context on the industry and occupation. These value sets that you're looking at, they're a part of the Cancer Implementation Guide that's required for Meaningful Use Stage 3 reporting for ambulatory cancer cases to Center for Disease Control and that particular standard has been developed based on a template of Consolidated CDA, so it reuses a lot of information from Consolidated CDA and adds on additional cancer-specific data elements, and some of the other data elements that we couldn't find in Consolidated CDA.

So the industry and occupation value sets that you see here are already part of the Meaningful Use Stage 3, so I thought it would be meaningful to reuse what's already existing, as opposed to, you know developing something completely new.

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

Well, I mean maybe they should be qualified though for what purpose they're reused for, I mean they're used for.

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

Social history, social history, industry and occupation; social history section in...

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

No, what I was really meaning...what I was meaning is that in cancer registries there's the energy and time to collect that detail, but if thi...but some of these could be pretty burdensome for clinicians to have to fill out in their social history; that's my only issue, my chronic concern. I think we should reuse them if...or subsets of them, but I think there's like thousands aren't there, thousands of terms?

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

Yeah, I mean I see your point, I mean maybe there are opportunities for the EHR vendors to provide functionality to, you know as you type, you fill in similar to you know populating problem lists; there are about 120,000 problem list...there are various tricks you can do to facilitate physician entry of problems. So, I think we can use some of those same principles or, if it's really too burdensome, create a subset of this subset.

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

Yeah, well maybe at least you could include some phraseology to qualify that this is already being used in cancer registries and some subsets or more, might be useful in the other area, but without you know, putting too much burden on the clinicians for recording.

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

But there are other...this is Kin Wah; so maybe a similar model can be adopted like in the race and ethnicity, because in the recommended value sets the most detailed one has over 900 different choices, but they are all...they are wrote up to two other reference value sets which have only five in one and two in the other. So maybe in clinical use and everyday can we use the shorter ones with the five most of the time?

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

Well yeah, but you need somebody to do that, yes, that would be good.

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

Or...this is Kim; we have three minutes left and I have one question with this one and it's probably directed to Dan. Is this one of those that needs the observation and observation value?

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

Uh, I mean I can answer that one; this is Mark. We already have a LOINC associated for each one of these data elements, so yes, correct.

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

Okay. All right. And I think we need to pause to open up for public comment or Brett, unless you wanted to bring up something else. I do have to jump off at 2:30, though, so.

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

Yeah, maybe we can...Michelle, you can open for public comment and I'll over...give a review of the homework assignment while we're checking to see if there are comments.

Public Comment:

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

Perfect. Lonnie, can you please open the lines?

Lonnie Moore – Virtual Meetings Specialist – Altarum Institute

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

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

Thanks. So for Sections II and III, just based on our progress, I think everyone can probably agree it's unlikely we are going to get to those by our July 27 presentation to the Standards Committee, at least to discuss everything in their entirety, so unless anything shifts with our timeline for that presentation, which we are having some internal discussions on and we'll get back to folks ASAP if that is the case.

But unless that does happen, our thought was to have the group take a look at Sections II and III with a fine-toothed comb and alert us if there are kind of any urgent, burning issues that need to be addressed and then immediately placed into those recommendations you would like to see in the 2017 draft ISA that will be released this summer. And other than that, the Sections II and III review, we'll move to Phase II of this task force along with some of the other topics such as looking at the projected addition piece and effect on research.

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

Does that suggest that I should filter the set I already sent? I haven't looked at them for a while or will you be looking at those anyway?

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

So we'll take a look at those, but if you can call out the ones you've looked at as this is something that urgently needs to be addressed...

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

Okay, I'll do it.

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

...that way we can kind of go through those over e-mail and discuss them on one of the upcoming calls before the Standards Committee presentation. And we'll remind folks via e-mail, since I know there are a few folks missing today.

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

Yeah, this is Susan Matney and I know the nursing industry has given feedback and I'll review that and make recommendations, because I agree with what their feedback is, so we get that in with this release, in Phase II.

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

And what I've heard...oh, sorry.

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

Go ahead.

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

And what I heard you say, Brett was Clem, it doesn't mean we're not going to get to all the ones that you came in, but it would just be part of Phase II, is that correct, Brett?

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

That is correct and so because, just based on our publication timeline, things that we...things that you think need to be addressed because there are factual inaccuracies or things that you know, just don't

quite look right that you want to see get implemented in the draft that happens this summer versus things that may be addressed in the final draft or the final edition that would be published in December.

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

And...

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

This is Michelle, so we'll follow up with an e-mail just reminding everybody of what exactly we're asking for and there are no public comments at this time. So thank you all and we'll talk to you again on Tu...on Thursday.

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

Thank you.

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

Thank you.

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

Thanks, bye.

Michael A. Ibara, PharmD – Private Consultant – Michael Ibara, LLC

Thanks.

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

Thanks everyone, take care.