



**HIT Standards Committee  
Semantics Standards Workgroup  
Final Transcript  
March 23, 2015**

**Presentation**

**Operator**

All lines are bridged with the public.

**Michelle Consolazio, MPH – FACA Lead/Policy Analyst – Office of the National Coordinator for Health Information Technology**

Thank you. Good morning everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Standards Committee's Semantics Standards Workgroup. This is a public call and there will be time for public comment at the end of the call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I'll now take roll. Jamie Ferguson? Becky Kush?

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Yes, here.

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

Hi, Becky. Andy Wiesenthal? Asif Syed? Betsy Humphreys?

**Betsy Humphreys – Deputy Director – National Library of Medicine**

Here.

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

Hi, Betsy. Eric Rose? Harry Rhodes? John Carter?

**John Carter, MBA – Vice President – Apelon, Inc.**

Here.

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

Hi, John. John Speakman? Margaret Haber?

**Larry Wright, MA – Program Manager, Enterprise Vocabulary Services (EVS); Biomedical Informatics Specialist – National Cancer Institute**

Larry Wright representing Margaret.

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

Hi, Larry. Mitra Rocca?

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration**

Present.

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

Rosemary Kennedy?

**Rosemary Kennedy, BSN, MBA, PhD, FAAN – Vice President for Health Information Technology – National Quality Forum – Associate Professor Thomas Jefferson University School of Nursing**

Present.

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

Stan Huff? Steve Brown? Todd Cooper?

**Todd Cooper – President – Breakthrough Solutions Foundry, Inc.**

Good morning.

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

Hi, Todd. And from ONC do we have Patricia Greim?

**Patricia Greim, MS, RN-BC - Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

Present.

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

Hi, Tricia. And with that, I'll turn it back to you, Becky.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

So thank you all for being here today and I apologize that I missed the meeting last week, so I'm hoping somebody will give us an update for anyone who wasn't present at the face-to-face meeting last week. And we are going to change the agenda just swapping the last two items because Todd Cooper's on the call now and he has to leave at the top of the hour, so we'll be allowing Todd to go first and then we'll look at the Content Workgroup comments. So, is there anything else Michelle or Tricia that we should say at the beginning of this call?

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

That sounds good, Becky.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

So, would you like to go ahead and go through the workgroup plan and maybe tell us what you'd like us to achieve on this particular call?

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

Sure. Thank you. What's up right now on the webinar is the Semantic Standards Workgroup; next slide. Our charge, just to remind us; next slide. Okay, this is where we want to look here. And Becky, I had promised to get the agenda out on Friday, and I did not get it out until this morning, so, what I wanted to just comment on was, there has been some...I have had some email traffic about the rapid pace that we're setting and the quick turn-around expectations.

And as we look at this Semantic Standards work plan, we can kind of see the aggressive schedule we've kept, almost...looks pretty much like every week meetings. The...going forward, what we have now is the NPRM, the release of the notice of proposed rulemaking with the request that will be made for comments from us, as well as ahead of us finalizing comments on the interoperability roadmap. So, we aren't...we don't have a breath in sight until late May, it looks like on our...on the pace that we've set.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

So, I don't know if there's anything we can do about that.

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

Yes, I just wanted...

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

Yeah, this is Michelle. So unfortunately the timing of things has just, it is what it is. I can say that things will hopefully die down a little bit after the May meeting when you all report out on the NPRM. We tried to set expectation from the start that we knew these things were coming and that there would be a fairly rapid pace. So hopefully it will even out by the end of the year; so we were meeting quite a bit between February and May and then the summer months might be quieter and then you might see things pick up again. So, we apologize for the drain on your time, but we do appreciate the commitment that everyone has shown to all these meetings and keeping up with us. And hopefully we can keep that going through the end of May and we just want to say thank you for all the time that you've committed.

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

Thanks, Michelle. The other thing that...there was an interim update, as you mentioned, at the HITSC meeting; the content for that update was reviewed on Monday and the meeting was on Wednesday, so that was also Becky a really quick turn-around and I know we got at least one comment in this week that there was a need to change some language around one of the items which, on review of the transcript, I

did do. And so, this is where we are. Looking forward we're due to come to cons...some final comments on the interoperability roadmap and also to transition to a plan to complete the NPRM. If we go to the next slide.

**Todd Cooper – President – Breakthrough Solutions Foundry, Inc.**

Before we do that, I have a question.

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

Okay.

**Todd Cooper – President – Breakthrough Solutions Foundry, Inc.**

Was there any feedback to the meeting last week, the SC meeting, based on the slides that were presented?

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

It was a slotted 15 minute report out; it was...I don't recall any public comments or...Michelle, do you recall any?

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

I think what he's referring to, and if you could please state your name, because I don't know who that was...

**Todd Cooper – President – Breakthrough Solutions Foundry, Inc.**

This is Todd.

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

Thank you. I think he's referring to feedback from the Standards Committee based upon what Jamie presented. I don't...

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Right.

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

...think there was anything too major, but...

**Todd Cooper – President – Breakthrough Solutions Foundry, Inc.**

Okay.

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

It was identified as an interim update and not a final report out and it was among I think 3 or 4 other updates, so...

**Todd Cooper – President – Breakthrough Solutions Foundry, Inc.**

Sounds good, thank you.

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

Thanks Todd. Okay, and so since we're looking at the work plan Becky and everyone, I just wanted to identify what sections we would be expected to review, it's another divide and conquer approach to the NPRM as we had with the roadmap and this is the current thinking about what sections of the NPRM we would want to review as Semantic Standards committee members.

Just a preview, preview's going ahead as the request has come in, if we go back one slide, the request that's on the table is to actually scope out complete...looking at the calendar, if we think that we have enough meetings scheduled in order to complete a final report out on the roadmap as well as reporting to the HITSC on the NPRM.

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

Tricia, this is Michelle, I think that that's something that we can do offline with the Chairs...

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

Okay.

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

...and walk through what's appropriate for each meeting.

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

Okay, great. So, that's what we'll be doing offline. Just kind of a preview of what's ahead. Any comments or questions?

**Larry Wright, MA – Program Manager, Enterprise Vocabulary Services (EVS); Biomedical Informatics Specialist – National Cancer Institute**

This is Larry. On the various things in the NPRM that were on the following slide, when would we be reviewing the details of those and the SME Reports?

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

Next slide. I'm...okay, so Larry, you're asking what would be the schedule for reviewing this content.

**Larry Wright, MA – Program Manager, Enterprise Vocabulary Services (EVS); Biomedical Informatics Specialist – National Cancer Institute**

Well I'm trying to figure out what to expect. We have sections and SMEs identified but I'm not clear when we get feedback from the SMEs, how that feeds into the schedule you were showing.

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

Yeah, this is Michelle; I think this is something that we probably shouldn't have presented yet. So today we're going to wrap up on the interoperability roadmap comments, hopefully and then during the next meeting we'll walk through a process for reviewing the NPRM and talking through how we're going to get through all of that. As Tricia mentioned, we might need to add additional meetings; hopefully not, we'll let you know. We'll plan offline with the Chairs and get back to you.

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

And I don't think we anticipated reports from the SMEs, so we...perhaps you recall, Larry, that when we looked at the roadmap we had points of contact within ONC that we could reach in to for additional information perhaps, if needed. So that's probably just an FYI who has the points in ONC for that content. And the NPRM stands alone, on its own for itself, so as...so just basically, as Michelle said, probably not as relevant to consider the SMEs as part of the slide.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Okay, so are there any other questions on what we're supposed to be doing today? We had two items on the agenda, one was to hear from Todd Cooper about devices and how devices aren't really being addressed yet, I believe and the other was our...there's quite a bit in these Content Standards Workgroup recommendations and I wasn't real clear on exactly what we should expect to get accomplished today, since people really haven't had a chance to review them. Do you have a recommendation Michelle or Tricia?

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

Let's bring up the healthcare device informa...well, we don't have slides for the healthcare device information, but let's just queue up that discussion, Becky, then. So...and also prepare to...the Content Standards Workgroup slides, we can display when we transition to that discussion. So, I think Todd was interested in introducing some comments about the healthcare device information related to semantic standards.

**Todd Cooper – President – Breakthrough Solutions Foundry, Inc.**

Right. So thank you very much. If you look through the published roadmap, you see devices mentioned in a number of contexts. One...primarily those contexts have to do with personal health devices, worn devices and how those devices might be brought in and wanting to have access to that information. The other is cybersecurity, so some of the cybersecurity challenges around devices used in the healthcare context and especially since the well-publicized hacking of a few different devices, including an implanted defibrillator or an insulin pump. There has been a large amount of interest, especially by the FDA around trying to advance medical device cybersecurity.

So, there was appropriate wording and mention on a few occasions in there. There's also some mention in the roadmap around the UDI, so the Unique Device Identifier that the FDA has rolled out. It's very much constrained to implantable Class III devices like a pacemaker, as opposed to broader application. And I did have chat with Jamie on Thursday or Friday, I forget which, about that and the challenges that the healthcare industry has around implementation of the UDI.

And I understand that, but what I...what is completely missing is any sort of mention about the inclusion of information that can be captured from devices in a standardized way. And so just to give you a little bit of background on that; today there are quite a few systems out there that have implemented and demonstrated even certified adherence to standardized device information that can be incorporated into EHRs. A large part of this is based on the ISO IEEE-11073 terminology. We've also, I think just in discussions I've had with LOINC on Friday, I think right now we've also mapped about 600 of the core monitoring parameters to LOINC, from 11073. And I know we've had similar kinds of activities involved in SNOMED CT as well.

But there are production systems out there that do this and so I think at this point, and especially given the state of the industry and the length of time around this roadmap, we really should have some wording that encourages the incorporation and utilization of device acquired information by these systems, especially to help drive decision support systems, not just flow sheets that clinicians maintain and other clinical algorithms, for example. So that's, as a...that's the observation and the request. I would like to at least have a common theme be something recognizing the need to have this added into the roadmap. I wasn't quite prepared today to give you specific wording of what might go into that roadmap, but I'm absolutely happy to discuss.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Thank you very much, Todd. Does anybody have any comments or questions for Todd or do you agree that we should get some wording to add?

**Rosemary Kennedy, BSN, MBA, PhD, FAAN – Vice President for Health Information Technology – National Quality Forum – Associate Professor Thomas Jefferson University School of Nursing**

This is Rosemary Kennedy; I just wanted to provide some support for what Todd just stated and maybe put forth a question. Would it be a separate section, do you think, from a device perspective, or would it be through the lens of the data type, if you will; for instance, vital signs. There are so many different ways to capture a blood pressure, which is important, in terms of clinical decision making either at the point of care; am I looking at a systolic or diastolic or is it a mean arterial pressure or an A-line coming from an ICU. So would it be through the lens of the information source, the data source or do you think it's important enough to have its own kind of grouping?

**Todd Cooper – President – Breakthrough Solutions Foundry, Inc.**

Grouping in terms of this is the device acquired data?

**Rosemary Kennedy, BSN, MBA, PhD, FAAN – Vice President for Health Information Technology – National Quality Forum – Associate Professor Thomas Jefferson University School of Nursing**

Yeah, yeah.

**Todd Cooper – President – Breakthrough Solutions Foundry, Inc.**

So I'll say a couple of things on that; number 1 is, to the degree that monitored data is often just more highly granular vital signs kinds of data, I would hope that as it gets aggregated that would be included in models or constructs that are...would be consistent regardless of how its acquired. It's just you have a higher level of granularity. There are data, though, that are not vital signs kind of data; for example, if you're monitoring the operation of an infusion pump, that's not monitored vital signs data, but it's really important to understand well, when did you actually begin delivery of this medication...are we still online?

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

Yes we are but...

**Todd Cooper – President – Breakthrough Solutions Foundry, Inc.**

So I have a sound track now.

**Rosemary Kennedy, BSN, MBA, PhD, FAAN – Vice President for Health Information Technology – National Quality Forum – Associate Professor Thomas Jefferson University School of Nursing**

Somebody put us on hold.

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

Hopefully the operator can catch that person.

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

Sounds like they have.

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

Sounds like they did.

**Todd Cooper – President – Breakthrough Solutions Foundry, Inc.**

And so there are classes of data that are unique, but are clinically highly relevant so I would anticipate having a specific call out about the need for integration of device acquired data, but then as that data supports other clinical data structures, they have it integrated as such. But then also where it is unique identifying, call that out, for example, around infusion pump informatics. What were...

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

So are there other questions for Todd? I'm sorry, Todd, go ahead.

**Todd Cooper – President – Breakthrough Solutions Foundry, Inc.**

There are definite areas that are out there that we would not include today, for example, automatically going out and controlling the device; that's still an area of research and standardization, it's not mature enough, I think, for this. But absolutely there's, like I said, there are production systems that support standardized informatics today, so that would be.

**Larry Wright, MA – Program Manager, Enterprise Vocabulary Services (EVS); Biomedical Informatics Specialist – National Cancer Institute**

Devices and imaging were areas that we flagged in the past as important to try and extend to include, how would this relate to the FDA CDRH standards and to DICOM?

**Todd Cooper – President – Breakthrough Solutions Foundry, Inc.**

Which are two different areas, right?

**Larry Wright, MA – Program Manager, Enterprise Vocabulary Services (EVS); Biomedical Informatics Specialist – National Cancer Institute**

Right.

**Todd Cooper – President – Breakthrough Solutions Foundry, Inc.**

So typically this is...whereas DICOM really focuses in on the imaging part and actually there are some parts of DICOM that reference these standards, for example, for body sites, for ECG representation, they are, generally speaking, a unique distinct set of devices. So, we would want to call out the difference between therapeutic, diagnostic and imaging kinds of devices. The FDA has been very closely watching this area, but they have yet to make any sort of pronouncements on this one way or the other, especially when it comes to integration of device acquired data into an EHR or other enterprise systems.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

So, would you all agree that we need to devise some language to add to this, and I heard Todd say that he would be happy to help draft some for our review?

**Todd Cooper – President – Breakthrough Solutions Foundry, Inc.**

Absolutely you heard that.

**Rosemary Kennedy, BSN, MBA, PhD, FAAN – Vice President for Health Information Technology – National Quality Forum – Associate Professor Thomas Jefferson University School of Nursing**

This is Rosemary Kennedy and I would highly support that and everything that Todd said. I think there are attributes, concepts, data elements that may come forth, looking at it from a device perspective, whether it's continuous infusion pumps or continuous vital signs measurement that would be addressed by having it as a separate section with some focus. So I'd be more than willing to help and support that in whatever capacity is needed.

**Todd Cooper – President – Breakthrough Solutions Foundry, Inc.**

That would be excellent.

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration**

This is Mitra Rocca from FDA, I would also support that and Todd, whatever language you develop, you can share it with me and I can run it by CDRH. I work at CDER, but I can run it by the Center for Devices, the experts there.

**Todd Cooper – President – Breakthrough Solutions Foundry, Inc.**

Excellent, thank you very much.

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration**

You're welcome.

**Rosemary Kennedy, BSN, MBA, PhD, FAAN – Vice President for Health Information Technology – National Quality Forum – Associate Professor Thomas Jefferson University School of Nursing**

And I'm working with the American Association of Medical Instrumentation and would be willing to reach out for input from that entity as well, who I think is working closely with the FDA.

**Todd Cooper – President – Breakthrough Solutions Foundry, Inc.**

And I also work very closely with AAMI. Who was that who was just speaking?

**Rosemary Kennedy, BSN, MBA, PhD, FAAN – Vice President for Health Information Technology – National Quality Forum – Associate Professor Thomas Jefferson University School of Nursing**

Rosemary Kennedy, I'm sorry.

**Todd Cooper – President – Breakthrough Solutions Foundry, Inc.**

Oh, Rosemary.

**Rosemary Kennedy, BSN, MBA, PhD, FAAN – Vice President for Health Information Technology – National Quality Forum – Associate Professor Thomas Jefferson University School of Nursing**

Sorry to forget to say my name, Rosemary Kennedy.

**Todd Cooper – President – Breakthrough Solutions Foundry, Inc.**

No worries.

**Betsy Humphreys – Deputy Director – National Library of Medicine**

This is Betsy Humphreys at NLM and I agree with what's been said here, I think we need to do something here about devices. Just in case anyone does not know, NLM is working with the FDA because we will be providing public access to the UDI registration data, as we do for the structured product labels for drugs. And that work is fairly well along and I would expect probably within the next couple of months, we will have an initial public release of the data on the registrations that have been made so far.

As Todd pointed out, it's initially on a ne...what they have now is on a subset of the devices that of course will be of interest to everyone and I guess it's over a period of years, isn't it Todd, before all categories of FDA regulated devices have to be registered in the database. But if you say the future is longer than the past, we should get to the point where if a UDI is entered in any part of a medical record, either because it is actually specifying the device that ran the test in a LOINC mess...you know, in a LOINC thing, or because it's a device that's at home with the patient or because it's a device that's implanted in the patient there should...we should be at a point where there's just a publically accessible place where you can look it up...

**Todd Cooper – President – Breakthrough Solutions Foundry, Inc.**

Yeah.

**Betsy Humphreys – Deputy Director – National Library of Medicine**

...from what information you have. So I would suspect, just the same way now people are coming in with various levels of data and running against our APIs to get the RxCUI for something of the SPL for something else, I imagine that we should be able to get to that point within some period of years here.

**Todd Cooper – President – Breakthrough Solutions Foundry, Inc.**

Betsy and Mitra, I guess one of the questions I had is, in the roadmap right now, it seems to only look at pacemakers or maybe defibrillator UDI; unless I missed something, it doesn't talk about the longer perspective. However, from our...I know from a device industry perspective and what the FDA is doing, as you said, it is intended to be rolled out broadly across all registered devices. So I was just somewhat surprised, I do know that Jamie indicated that there is significant inpu...push-back in the industry

relating to the fact that once you get off of the most critical devices, like a pacemaker, where the patient's safety issue is extremely high, that on the other class devices, the patient safety issue is high, the main problem there is around a supply chain management and really more an operational impact that this would have.

**Betsy Humphreys – Deputy Director – National Library of Medicine**

Yeah...

**Todd Cooper – President – Breakthrough Solutions Foundry, Inc.**

So I don't know what the story is there, but I would sure like the roadmap to speak to more the broader context, as you just described, Betsy.

**Betsy Humphreys – Deputy Director – National Library of Medicine**

Yeah, I think that the issue is that I'm sure that there's always the tension between saying well here's a place we want to go and these are issues that we want to have happen and potentially laying down some specifics in advance of any of us knowing what all the problems are and what really needs to be done. So, I'm sympathetic with the roadmap drafters on that latter point. But I would agree that I think it would be very useful for there to be at least a discussion of this and the fact that there is going to have to be serious attention to this going forward...

**Todd Cooper – President – Breakthrough Solutions Foundry, Inc.**

Yeah.

**Betsy Humphreys – Deputy Director – National Library of Medicine**

...to identify where the real benefits lie...the biggest benefits at the affordable cost lie and gradually work our way to what might be closer to an ideal state in this space.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Okay, any other comments because it sounds like we have pretty broad agreement that we should draft a little language to give input? All right, if not, then should we go to the Content Standards Workgroup comments? I'm thinking, although I missed some things last week while I was gone that we had some homework to comment on these and I know that Betsy Humphreys and Mitra Rocca both sent in some comments. Did anybody else send in comments, because I believe those are the two sets that Tricia got?

**Larry Wright, MA – Program Manager, Enterprise Vocabulary Services (EVS); Biomedical Informatics Specialist – National Cancer Institute**

Becky, I sent in some very general comments, but...

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Oh Tricia, did you see those?

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

Umm, I did see a message from NCI, I thought...I didn't know that they were related to the...I thought it was...I will go back and look at that message, Larry, because I misinterpreted that as a different type of comment. So, it was...so...

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Is that...were they intended on these Content Standards Workgroup comments, Larry?

**Larry Wright, MA – Program Manager, Enterprise Vocabulary Services (EVS); Biomedical Informatics Specialist – National Cancer Institute**

So they were and basically it was, apart from a comment on the sort of very rushed review schedule and not being able to do a more thorough job of it, for which we apologize, there seemed to be a lot of things that were missing from the original 60 pages of Content Standards Workgroup comments in the slide deck before that, particularly in areas like the need to include a broader range of standards, particularly research and international ones and hoping that there would be time to go back to what the Content Standards Workgroup also try and correct that because they were in the original comments and somehow got lost.

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

And I take responsibility for misunderstanding that, Larry. So the...if I understand what you're saying it's that the homework that was distributed, the slides that were distributed were not a full reflection of the Content Standards discussion related to semantics.

**Larry Wright, MA – Program Manager, Enterprise Vocabulary Services (EVS); Biomedical Informatics Specialist – National Cancer Institute**

Correct.

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

Because the Content Standards...I'm...I...so the Content Standards discussions related to content were...they were supposed to separate out what was related to standards and send them to us. And so the concern I'm hearing now that I obviously missed earlier is that really what we got was not a full reflection of at least discussions that you've been part of on the Content Standards committee.

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

This is Michelle, just to clarify. So the Content Standards Workgroup also created a small subgroup that I think did the work that Larry's referring to; those are integrated into the comments that were shared with this workgroup.

**Larry Wright, MA – Program Manager, Enterprise Vocabulary Services (EVS); Biomedical Informatics Specialist – National Cancer Institute**

Well actually it was both that small workgroup, but also the full meeting as reflected in the slide deck dated February 25, slides 27-30 in particular.

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

So the full set of comments from content aren't shared here, it was just the items that we thought were more appropriate for this group to be discussing. So maybe we can follow up with you offline, Larry, to make sure that we have the full extent of comments and there isn't any confusion.

**Larry Wright, MA – Program Manager, Enterprise Vocabulary Services (EVS); Biomedical Informatics Specialist – National Cancer Institute**

Okay.

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

Thank you.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Yeah, I think that would be helpful for some of us...this is Becky, and I had a presentation to the Content Standards Workgroup last Monday and I was surprised to see that only one point was pulled out of that entire discussion. So...

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

Yeah, so Becky that's exactly the small group...

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

...I'm feeling the same way that Larry is, yeah.

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

So just to clarify, that's the small group that I'm referring to and those comments are no way shared with this group.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Okay.

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

We're trying to differentiate and keep things separate.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Oh, okay.

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

So I know...

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Sorry, I guess, so a...

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

No, no, I mean I understand.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

...a few of us are on both of these.

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

Exactly.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

All right, that helps me.

**Larry Wright, MA – Program Manager, Enterprise Vocabulary Services (EVS); Biomedical Informatics Specialist – National Cancer Institute**

Right, so I did express concern that the points you had raised there weren't shown, but knew that was a small working group within the Content working group.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

So those comments will still go in and is there a review process for those, with the small group?

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

Yeah, so the small group...so Content Standards actually has a call today and the small group work is going to be reported out during their call this afternoon.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Oh, okay. So, what we have to do on this phone call is look through these few slides and see if there's anything else we need to discuss. And in the short time I've spent with them, it looks like there's some...I'm not sure if they're conflicting comments or they're just not totally aligned in my head. So, maybe we could go through and see if there's anything you all would like to point out that we should in particular be commenting on. Because when I looked through these slides, especially slides 4 and let's see, the last two 11 and 12 seemed to have some things that we might need to resolve in terms of the comments that we want to give back to this group.

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

I think there's even some confusion in the intent. So what happened is, Content Standards and this group were assigned the same section of the roadmap and we tried to differentiate the work a little bit. And these items were items that we put in a parking lot for Content Standards, because we felt that they were more appropriate for this group. And so the hope was that these comments aligned with things that your group were saying and that these comments could be integrated into your comments on the roadmap. If that's not the case and you have, you know, something gives you heartburn, then we

need to identify those and work with Content Standards to better understand where they're coming from and it doesn't...it won't seem like something that this group will want to include in their comments. Does that make sense?

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Okay, so how would you suggest we give you the best input here?

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

So maybe, like you said Becky, we can walk through these and if there's anything that we...this group disagrees with, let's talk about that. And if the group is in agreement, then it's something that we can easily integrate into Semantic Standards comments when they're submitted.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Okay. All right. And just full disclosure, I'm working off the slides because something's wrong with my Adobe Connect, so if we just go to the slides on the Content Standards Workgroup. On slide number 2, is there anything that we should be commenting on or is this just more or less...

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

This is the summary slide, right? The...

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Yeah. So we should probably start with slide 3, with the comments.

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

Okay. And we did get two comments related to this slide...

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Yeah, I saw that...

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

That's displayed at the end, but I could read them as we're looking at them here. I really didn't know how to incorporate those, so I...since both comments were related to...since there were two comments on slide 3, we had a comment that as dis...they were both related to the very last bullet, suggested vocabularies and code sets do not align well with widely used research and clinical standards, including those defined by FDA and other US and international agencies and SDOs such as CDISC. Specifically the need for MedDRA terminology to document and report clinical trial adverse events is not addressed. That was the comment that got two comments from us and if we advance to slide 11, we can have those displayed, but I can read them. One comment was we had previously discussed that all EHRs should not have to deal with MedDRA and the fact that some EHR products may be used to record clinical trial data

should not lead to an additional and duplicative vocabulary requirement for all EHR products. This is a place where mapping is a logical approach. NLM and NCI are discussing how to do this for a subset.

And the other comment was FDA follows an open consensus-based process to develop and maintain data standards in collaboration with accredited SDOs. Adverse event reporting is not captured as a use case in this roadmap and not all centers at FDA leverage MedDRA for clinical trial adverse events.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

I think Mitra and Betsy are both on this call.

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration**

Yes.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

What would you suggest we do with this?

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration**

I was thinking to remove the example of MedDRA because CDRH actually uses SNOMED CT for adverse event reporting.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Um hmm.

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration**

And then the other thing...

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

So just remove the last sentence?

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration**

The last sentence, yes. And then the first one, FDA actually we don't develop standards, we work with accredited SDOs.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Right.

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration**

So...

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

So on that last comment there are some changes we need to make, Betsy, I'm sorry, did you say something?

**Betsy Humphreys – Deputy Director – National Library of Medicine**

No, I didn't. I do feel that obviously the requirements for industry that exist today in standards...in regulations and whatever, in terms of reporting to FDA are very important, but I really think we need to resist moving those requirements back into a requirement that would affect every EHR product in the country.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Yeah, well this one bothered me because the presentation I made to the Content Standards Workgroup on Monday, they asked me to make a comment about MedDRA, but 95% of the presentation was how could we make sure that we're aligning the handoff between EHRs and what we need for research and it was not about MedDRA or AE reporting. So, I think this kind of got blown out of proportion.

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration**

And this is Mitra, we actually, one of our own comments was to minimize mapping, so...

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Yeah.

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration**

...without mapping, I don't know how...we don't want to push MedDRA into a healthcare system, so we are always going to be using SNOMED CT, we will need, like in this scenario, it would need the mapping from SNOMED CT to MedDRA.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Right.

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration**

We don't want to add MedDRA into the healthcare standards because we'll never get to SNOMED CT.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Right.

**Larry Wright, MA – Program Manager, Enterprise Vocabulary Services (EVS); Biomedical Informatics Specialist – National Cancer Institute**

So, this is Larry and we weren't clear. Our impression from EHRs that we interact with was that there was much wider use of MedDRA than of SNOMED CT, but it would be interesting to have some better information about that.

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration**

Actually the EHRs don't use MedDRA at all.

**Larry Wright, MA – Program Manager, Enterprise Vocabulary Services (EVS); Biomedical Informatics Specialist – National Cancer Institute**

Well, the experience that I've, in talking with clinicians and nurses around NCI was that they had seen much more use of it in the EHR environment that they were familiar with than they had of SNOMEDs use. But, as I say it wasn't something where we found solid data, so it's an impression. But it is a widely used standard for a variety of purposes and so, which includes all cancer clinical trials.

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration**

Yeah, the NCI uses it for their electronic data captures, but the EHRs don't use MedDRA, it's always being mapped, like currently at FDA internally the safety evaluators, when they receive the adverse event, if they use ICD-9 or 10, they are mapped to MedDRA, or if they use SNOMED they are mapped to MedDRA for the adverse event reports. But the adverse event report is not even in the appendix as one of the use cases on this roadmap.

**Larry Wright, MA – Program Manager, Enterprise Vocabulary Services (EVS); Biomedical Informatics Specialist – National Cancer Institute**

So you're saying the roadmap doesn't cover adverse events?

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration**

No, not at all; they have allergy, but not adverse events.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Yeah, I've always had a question too about why some people think that adverse events should be defined differently, and I think that's an important semantic issue we should address because I'm not sure why you would have a different definition for an adverse event in healthcare versus research. And if so, we need to explore those definitions, I think. So, if I look at these two sub-bullets on page 3, slide 3, if we removed the last sentence, would people be okay with what the Content Standards Workgroup wrote? That's what I think I heard Mitra suggest.

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration**

Yes, remove that and then also that FDA collaborates with accredited SDO in development of standards.

**Larry Wright, MA – Program Manager, Enterprise Vocabulary Services (EVS); Biomedical Informatics Specialist – National Cancer Institute**

To remove the FDA collaboration?

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration**

Yeah, it was in my sentence, I think it actually...

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

I think she just does not want it to sound like FDA is developing standards.

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration**

...yeah, developing standards. Yeah, right, yes. I don't like that.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

So we need to word it so that it doesn't...it couldn't be inferred that way.

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration**

Yes.

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

So we would rem...the proposal on the table is to remove the last sentence that starts with "specifically," and...

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Right.

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

...and then if we also included...I mean, if we also removed the phrase, including those defined...if we also removed FDA from the sentence "including those defined by FDA and other US and in...if we just said including those defined by US and international agencies and SDOs, would that...

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration**

That would be good.

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

...be better?

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration**

Yes, that would be better.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Can...so, would people be okay with these two sub-bullets if those changes are made?

**Larry Wright, MA – Program Manager, Enterprise Vocabulary Services (EVS); Biomedical Informatics Specialist – National Cancer Institute**

Okay.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

I'm not sure why those are sub-bullets either, they don't seem to fit with the C-CDA 2, but maybe I'm missing something in the HL7 v2.

**Larry Wright, MA – Program Manager, Enterprise Vocabulary Services (EVS); Biomedical Informatics Specialist – National Cancer Institute**

That was one of the surprises for me as well because the comments from the full Content Standards discussion had been that those were top level points rather than tied to C-CDA in particular.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Yeah. Can we just pull them out as full-fledged comments as opposed to sub-bullets?

**Larry Wright, MA – Program Manager, Enterprise Vocabulary Services (EVS); Biomedical Informatics Specialist – National Cancer Institute**

I think that would be more accurate and clearer.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Okay, any other comments on this slide 3? Tricia, did you get what you needed on this one?

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

Yes. Umm, yes.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

And maybe we address slide 11 as well now.

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

Yes. One...

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Should we go to slide 4?

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

Sure. We could just go to slide 12; I think here and see 4 and the comment.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Slide 4 and is it the red comment on this slide or is there another comment?

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

This is just copy and paste from slide 4. Umm, Betsy, what argument are you speaking to on this slide or do you have the visual?

**Betsy Humphreys – Deputy Director – National Library of Medicine**

I have it now. I just...I think probably I just don't...I just found it very confusing so I couldn't get at what they were getting at. Maybe if I had more complete comments or something, I just was confused by it. But...umm.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Is that the comment for page 77 or which...the whole thing?

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration**

Page 79, Becky.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Page 79.

**Betsy Humphreys – Deputy Director – National Library of Medicine**

I did not think I was commenting, maybe I gave the wrong...well, no wonder we're all confused, I probably gave the wrong slide reference, I better go back and look through this deck. Let me see if I can find it. Ignore this for now.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Okay, are there any other comments on slide 4?

**Larry Wright, MA – Program Manager, Enterprise Vocabulary Services (EVS); Biomedical Informatics Specialist – National Cancer Institute**

Well, I will confess I found it confusing, too, if that's the one Betsy found confusing, then we agree.

**Betsy Humphreys – Deputy Director – National Library of Medicine**

I was looking at some comment and I don't know who made it, but it was sort of like it was a comment that said that we could separate out semantics and structure and something or other and there were three categories or something and I just didn't follow it and it made it sound to me as if he was commenting that somehow we could divorce the terminology from the structure that was conveying the terminology, which I thought was a little...

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Is it...

**Betsy Humphreys – Deputy Director – National Library of Medicine**

...over the edge, but I...

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

It says the section on content structure standards is not ideal, the content is often considered to be the codes, numbers and text that lands in the field. It's better to call it message structure standards than describe the fields or data elements to be packed together for a particular purpose and add information about groupings and repeats. Is that part okay or is that confusing?

**Betsy Humphreys – Deputy Director – National Library of Medicine**

No, I was okay on that, I just...I don't know, there was a sense in there...there was a...one of the sentences in there I just didn't know whether the person was getting at this notion that...you know, I thought that they would...the notion of binding terminology and structure and I didn't want it thrown overboard, but they may have not had any intention of doing that.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Well their slide 5 talks about semantics context and content, vocabularies, dictionaries and code sets and format and structure.

**Betsy Humphreys – Deputy Director – National Library of Medicine**

Yeah, maybe it was slide 5 that I had really a problem with.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Yeah.

**Betsy Humphreys – Deputy Director – National Library of Medicine**

But it doesn't, as I say, I had a feeling I wasn't understanding the comment so, it may...

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

So Michelle, if we go back to where you started, are we supposed to just pull out a few of these that we agree with and pull them into our comments, since they were semantic?

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

Yes.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

So it sounds like we don't want to pull this in because people are finding it very confusing and it...

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

Sounds like it.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

...it sounds like we're trying to split hairs here since we've already got Content and Semantic workgroups that we're trying to divide up anyway.

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

Yes, Michelle, was the...from what I understood the intent was for the Content Standards Workgroup to share with the Semantic Standards Workgroup the comments that might inform our report to the HIT Standards Committee, but we're under no...

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Okay.

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

...we are under no mandate to use the comments or incorporate them.

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

Right. So as Becky said we'll just pull out the pieces that we agreed with and there's a lot here that it sounds like it's a little bit confusing, so we probably won't...

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Yeah, so it sounds like we should take what's on slide 3 and then take those sub-bullets into high level bullets. Slide 4 we may need to go back to and slide 5 we're going to ignore? Is that where we are?

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

Let's go...yeah, go ahead. Thanks for the summary.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

So if that was the confusing slide for everybody, then we'll just not take slide 5, because it sounds like they're trying to do definitions of what we're trying to achieve here. So, do you want to go back to slide 4 and see if people want to pull any of these comments into what we're going to use? I personally find slide 4 a little confusing, too; but that may just be me. I'm not sure what to do with it. Does anybody see slide 4 the comments that you want to use from our group? Everybody's quiet on this one.

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration**

Hi Becky, this is Mitra, I don't see our comment.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Well, it's the slide 4, page 77 and 79, they're asking us if we want to use any of these comments, but to me it sounds...

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration**

Uh huh, okay.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

...kind of like an internal discussion.

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration**

Okay.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

It doesn't sound like a comment on the roadmap to me, but I'm open if somebody sees it. Okay.

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration**

No.

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

I think we should...

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Maybe hearing none, we move to slide 6.

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

Sorry? Yes. I'll take the silence to mean that we shouldn't include it.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

It wouldn't mean an inclusion, okay, so we're...let's use some things off of slide 4, let's go to slide 6 now with proposed common clinical data set. Can you all see the comment on page 6 of the slides, page 80 of the roadmap.

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

Six.

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration**

Yes.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Yeah, we had some pretty general comments on this common clinical data set, one being that we didn't think it was the data set and that it needed a lot of work and a lot of vetting, so I'm not sure that this is going to add anything, although there are some specific considerations we might want to add to our general comment around smoking status, care team members and DICOM. Do you all want to use this comment?

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration**

This is Mitra Rocca, yes, the smoking status that is a good comment.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

So maybe these could be sub-bullets to our prior big comment that we need to do further vetting of the proposed common clinical data set, would that work?

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

We could do that.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Okay.

**Rosemary Kennedy, BSN, MBA, PhD, FAAN – Vice President for Health Information Technology – National Quality Forum – Associate Professor Thomas Jefferson University School of Nursing**

This is Rosemary, I would agree with that.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Great. Okay, moving right along, slide 7. Let's see, in order to support exchange across the continuum of care and in support of a learning health system interoperable data formats must adopt for care settings. Do you all see some things on this slide 7 that we should adopt? I don't see anything wrong with this

comment about needing a continuum of care, is it...behavioral health, long term and post-acute and community service providers. I don't know what exactly this is saying other than we should have semantics that support all of these things.

**Rosemary Kennedy, BSN, MBA, PhD, FAAN – Vice President for Health Information Technology – National Quality Forum – Associate Professor Thomas Jefferson University School of Nursing**

And were all of those things included within the scope of the roadmap or is it just saying that...

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Yeah, that's a good question.

**Rosemary Kennedy, BSN, MBA, PhD, FAAN – Vice President for Health Information Technology – National Quality Forum – Associate Professor Thomas Jefferson University School of Nursing**

I don't...in and of itself, one...I wouldn't disagree with it...this is Rosemary. But how does this align or not align with the overall scope of the roadmap or would it be something for future consideration, question?

**Betsy Humphreys – Deputy Director – National Library of Medicine**

One of...oh, excuse me. This is Betsy. One of the things that I think we want to avoid is ending up with an actual different underlying standards and format for exchange.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Right.

**Betsy Humphreys – Deputy Director – National Library of Medicine**

We want the formats that are the standards to accommodate these cases, but we don't want them to develop...we don't want to develop different parallel ones that would be a mess.

**Rosemary Kennedy, BSN, MBA, PhD, FAAN – Vice President for Health Information Technology – National Quality Forum – Associate Professor Thomas Jefferson University School of Nursing**

Yes it would be.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

So the way it's written, you could interpret that that's what's going to happen and so if we're going to use this, it sounds like we need to reword it.

**Betsy Humphreys – Deputy Director – National Library of Medicine**

As I recall, I felt that there was a potential...I thought that there was something hinting at that in the roadmap itself.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Maybe we should have a general comment saying just what you said, that we...

**Betsy Humphreys – Deputy Director – National Library of Medicine**

Yeah, I mean, I think we want...

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

...down to the semantics should...

**Betsy Humphreys – Deputy Director – National Library of Medicine**

...to accommodate all of the care wherever it's delivered and we certainly want to accommodate interaction with patients and so forth, but we don't want to do it by having a different standard for each area.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Right. Can we say that? Tricia, could that be our comment?

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

Our comment would be could you repeat...

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

The semantics should accommodate all of these different continuums of care in different settings, but they shouldn't be different for each one, it should be...

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

Okay. Yeah.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

...standard.

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

Yeah. They shouldn't be setting specific, okay.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Yeah, Betsy probably has a better way to say it, but that's the message I think we need to get across from this one.

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

Okay.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

There's some more on page 81 on slide 8. This looks pretty detailed. I'm sure it's right, but I'm not sure we need to go into this much detail on our comments. Does anybody see something on page...slide 8 that we should pull out? Well, hearing none, why don't we go ahead to slide 9? If somebody wants to come back to slide 8, we can, because that was the same page 81 of the roadmap.

So page 82, slide 9, are we all looking at slide 9?

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration**

Um hmm, yes.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Okay. Anybody see something about semantics that we should pull out of this one? Probably down in the third one. I guess I could see a comment that we could pull out of this that talks about versioning and how to maintain the standards in a way that they're easily downloadable or easily accessible. Anybody else see another comment in here? No?

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration**

No.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Should we go to slide 10?

**Betsy Humphreys – Deputy Director – National Library of Medicine**

I think we've already made the comment about...

**Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration**

Yeah, we did NIEMS.

**Betsy Humphreys – Deputy Director – National Library of Medicine**

...NIEM in our own comments, haven't we.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Okay, yeah, we did. We did. Umm, so the next two slides, slides 11 and 12 we already addressed before. So, does anybody see any other comments we'd like to pull out of here from the Semantics Workgroup? Okay, Tricia, Michelle, is this what you needed from us?

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

That was perfect, thank you Becky.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Okay, well is there something else we should do on the agenda, otherwise I imagine if anybody thinks of something today that they missed, they can still send it in, but otherwise, I guess you have what you needed from this workgroup today. Would you like to talk about the next steps?

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

Sure. We have our long version of the comments and consolidated comments and then we also have the reminder from Jamie that even if there was perhaps a missed opportunity to come to consensus about any of the comments, that that didn't preclude people putting those comments forward under their own name...

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Right.

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

...but that, yeah, so that was just something I wanted to emphasize.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Yeah, so anybody who wants can go ahead and submit comments on their own on the roadmap and that these will come from the Semantic Workgroup.

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

Yeah, so I think for next steps, we'll take the few things that we pulled out from the Content Standards Workgroup, add them to our comments that we've already included and this will really be the final work for the interoperability roadmap. We'll share that with the workgroup via email so that everyone has an opportunity to take one final look before we finalize.

And we do have some time before the meeting in April where this will get reported out, so, if there are changes that need to be made we can talk about them offline, but then bring them to a future meeting. But if not, then otherwise we will transition to commenting on the NPRM. So we'll meet with Chairs offline to do some planning and then share our first meeting about the NPRM will really be about process, talking through what the group has been assigned, how the group is going to get through all the work and then we'll dive into the NPRM.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Okay.

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

Michelle, this is Tricia. I was attempting to come off mute and I disconnected myself and I am on speakerphone now and Matt Rahn is here.

**Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology**

Hi, this is Matt Rahn with ONC. I just want to comment on slides 4 and 5 of this real quickly, just to kind of give a little bit of oversight. I was trying to talk during the call, but I was on listen only mode apparently and no one could hear me, so if you could go to slide 4, please.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Right. Okay.

**Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology**

...I just wanted to...okay. So on slide 4, page 77, Clem was just saying that the definition of what we have for content standards should be changed to what he has there. I understand if you want to take it or leave it, that's fine, but that was on page 77, which is technically out of scope for our workgroup anyway, but we thought that it might be good for you guys to review. Page 79, the...Marjorie's comment was...there really isn't a comment there because that's a direct copy and paste from the roadmap itself. And then Clem's is just adding the fact that LOINC isn't just for lab tests, but for vital signs and other observations. So, I'll just add that comment there.

And then slide 5, please. So on page 78, there's the categories of standards and this is just Rich's thought on how it should be structured instead of how we have it right now. So I think that's where he was going at in his comment there. So I just kind of wanted to put that out there. If you guys have any other comments or questions, I can follow up with Rich or Andy, because we do have a call today at 1. If needed some of you guys can call into that if you think that would be necessary.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Okay great, that's helpful. I guess I thought ONC had defined content and semantics around these two workgroups, so I might suggest we leave that up to you all rather...unless somebody has some more comments to provide in that regard. That was helpful context, thank you.

**Matthew Rahn – Program Analyst, Implementation & Testing Division, Office of Standards & Technology – Office of National Coordinator for Health Information Technology**

No problem.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

So, is there anything else we should do on this call or are we finished?

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

I think you're...

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

I think we're finished.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Okay, all right. Thank you all for guiding us through that so we knew how to interpret what you wanted.

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

So it sounds like Becky if you're ready, we'll go to public comment?

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Sure. Think so.

#### **Public Comment**

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

Lonnie or Caitlin, can you please open the lines?

**Lonnie Moore – Meetings Coordinator – Altarum Institute**

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

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

So just while we wait for public comment, just a reminder to those on the phone, we'll do a summary of today's discussion intertwining any comments that we thought or...like the group agreed with and we'll share those via email that you all can see one final time and give any final feedback before we finalize the comments on the roadmap and prepare Becky and Jamie to share them at the Standards Committee meeting in April.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Great.

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

And it looks like we have no public comment. So thank you everyone.

**Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)**

Thank you.

**Patricia Greim, MS, RN-BC – Health Scientist, Standards Division, Office of Science and Technology – Office of the National Coordinator for Health Information Technology**

Thank you.

**Betsy Humphreys – Deputy Director – National Library of Medicine**

Thank you.