

NRDS Policy and Governance Working Group

Monday April 25, 2016

Meeting Minutes

Agenda Topics

Project Update - Neesha provided an overview of the project updates and noted the agreement to use the same question and answer set, formatted in the same way for transmission to the NCI (how it is used in Rave). Currently the AE/SAE content are the items that are completed; the OPEN content is still in review (see presentation).

- Angela: We may be collecting OPEN items with more granularity than the overall standardized elements.
- Dianne: We will be working on these tomorrow in the Content Meeting.
 - Angela: It would be helpful if we note the ramifications of agreeing on a standard
 - Shauna: I agree, it would be good to see how the standards will affect.
 - Dianne: We have noted that when approved, it will be used “as-is” in Rave.
 - Shauna: I have emailed a note saying that we can provide feedback but that we are not comfortable with agreeing to the overall use of the standard.
- Judi: We originally thought it would be the name of the data element and then we found out there was more of the data element that needed to be standardized.
 - Angela: It is still outstanding to figure out how SWOG will map but I do not have a problem with the ones identified.
 - Dianne: The question needs to be standardized and valid values need to be collected in Rave, unless you do not need a valid value (i.e. omitting female for prostate cancer).
 - Judi: What are the fields in Rave that corresponds to these?
 - Dianne: Question Text = Field Label and the Coded Values = User Data String but there are caveats with the question text. The OID would need to be standardized as well.
 - Shauna: We originally had fields that needed to be integrated but now I feel that we are standardizing for the sake of standardizing.
 - Dianne: NCI/CTEP did identify that we started with integration but that would not necessarily be the only step. We should take the opportunity to standardize as much as possible. The items that have more granular options, that may be a better candidate for the mapping tool.
 - Neesha will add those points to the Content Documentation
- Shauna: Do you have a sense of when it will be completed
 - Neesha: We noted before that we expect 3 months after the changes are approved; it will be updated in the global library.
 - Mike: We were talking about 3 months after we implement, all trials will need to be compliant. If you need an extension, those can be done on a case-by-case basis.
 - Shauna: That sounds fair.
 - Judi: Do we know when the standard form would be available to put into our Global Library?
 - Neesha: We are still waiting to formalize the OPEN Content for the 3 forms; once those are done, we can start testing with the pilots. We are hoping to do this within the next 4 weeks.
 - Shauna: Do you have an anticipated timeframe for pilots?

- Neesha: We are only going to do 2 pilots and then provide to all centers. It will be about a month to a month and a half to test with the pilots. So, about 4 or so months before going live with this.

NRDS Compliance Criteria – Neesha Desai reviewed the compliance criteria proposed.

- Shauna: Does this statement apply to all? This may work for OPEN but this will not work for some of the items, i.e. some CDUS.
 - Judi: Are you thinking because the data elements will be mixed in with some that are not standard.
 - Neesha: We can note that it will exclude the CDUS Content
 - Judi: With OPEN we know there are elements that must be there and same with SAE but for CDUS reporting, there will be a core set of elements right? There may be variants of some data elements depending on the characteristics of the study.
 - Mike: We have discussed this, if it fits, you would use the complete list and if it is not applicable, then you would not use the complete list. Tweak the 3rd bullet and add a sub-bullet noting, clarifications for when the full list does not apply. ****Mike and Neesha** will work on this offline.
- Janice: You need to add a criteria to check for the question text (Neesha added during the meeting to the slides)
 - ****Neesha and Dianne** to work on the text
- Shauna: Can you please provide the full text for the acronyms and the equivalent Rave item
 - ****Neesha** to add
- ****Neesha** to add recommendation for the style guide

NRDS Workflow Template Content

Intake Form

- Judi: Under the Purpose, this is where they add the rationale for why they are requesting the exemption?
 - Neesha: Yes.

NRDS Standards Compliance Report

- Shauna: This is what we will get back?
 - Neesha: Yes

NRDS Compliance Tracking Log

- Neesha: This one will be tracking the status of the review; I will add a field of reason for non-compliance
- Judi: We need to include a listing of the non-compliant and the reason.

Exemption Assignment Findings

- No comments

Impact Analysis

- Neesha: This notes, if changes are made, what systems will it impact, changes that will need to be made, are there any larger changes that will be required.
- Dianne: This comes into play if there is a change to a standard and it shows the possible ramifications downstream.

****Neesha:** I will add the templates on a Word Doc and add them to the larger Policy Doc.

Next Steps

- Review Roles/Responsibilities based on ISO Standards
- Review drafted workflow templates

Attendance:

Name	Affiliation
Shauna Hillman	Alliance
Mike Montello	CTEP
Judi Manola	ECOG-ACRIN
Andrea Denicoff	NCI
Dianne Reeves	NCI
Janice Knable	NCI
Christina Warmington	NCI - Essex Management
Neesha Desai	NCI - Essex Management
Jennifer Thomas	NRG
Angela Smith	SWOG
Rodney Sutter	SWOG
Diana Vulih	Theradex