NRDS Content Working Group Tuesday June 16, 2015 Meeting Minutes

Action Item	Who	By When
Send the screen shots of the caAERS Forms to the working group	Neesha Desai	6/19/15
Send out meeting minutes	Neesha Desai	6/22/15

Agenda Topics

Meeting Recap – Neesha Desai welcomed the callers to the meeting and provided a brief meeting recap from the last meeting. She announced the results of the poll.

- Majority of the organizations voted to start with the caAERS integration forms, so that is what this group will start with.
 - OPEN Demography
 - NCIC
 - Theradex
 - o caAERS
 - ECOG-ACRIN
 - Alliance
 - NRG
 - COG
 - SWG
- The OPEN Demography content will be Phase 2 of this project.

Determine/Prioritize caAERS forms

The group agreed to start with the Adverse Event Forms. There are a total of 4 forms.

• Peter noted that it is too late to include this on their pilot but agreed that this was a good place to start.

The group reviewed the rest of the caAERS forms and decided to remove Patient Status: Baseline, Patient Status: FUP, and Patient Status: Tri Interventional because it can be different across LPOs.

Standardization Strategy

Dianne Reeves discussed the strategy this group will be using to make this content a standard:

- 1. The group will first work through the content on the caAERS Integration Spreadsheet, by form, and focus on the actual variables, coded values and their meanings and definition's along with the use or non-use of NCI CRF standards.
- 2. The group is still determining if they want to look at each form for formatting of the question text, after the content review is done, or to finish the 4 AE forms then review for question text formatting.

Adverse Event Questions Forms

- Date of First Course/Cycle
 - The group did not make a decision on the question text in terms of using both course and cycle or only using one.(course/cycle vs. 'cycle')
 - The group agreed to keep the words "derived" in the instructional text.

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- o The Alliance removed course and kept cycle in their pilot as the question text.
- Vanitha: We kept both Course and Cycle in the question text because they are different elements for us but I do not mind changing on the next release.
- Peter: We review the treatment courses, so we would want the question text to reflect that in some way. It would confuse our users if they saw course everywhere else but cycle here. We only report the course.
- Dianne: But you are using the term 'course' as a cycle in this case, right?
 Peter: Correct. We concur that there are several cycles in a course.
- Katie: For caAERS, you would want to have the date of the first cycle, not just the first course?
- Comments Character
 - The group had no additional comments or changes.
- Attribution to study intervention
 - o The group had no additional comments or changes
- Treatment assignment code (derived)
 - Populated from OPEN to RAVE from RandoNode Provided by CTEP
 - Theradex can enter a new TAV at every course for adjustment to change in therapy (Course Initiation Form)
 - Peter: We do have it in our enrollment that comes from OPEN, but as the study progresses, they may change their assignment code. They do not have to go back into OPEN to change it.
- Adverse Event Final Assessment Date/Treatment Reporting Period End Date
 - This will be taken back as an action item to review which one is appropriate. There are two different elements discussed during the meeting.
- Adverse Event ID (derived)
 - The group had no additional comments or changes
- Treatment Assignment description
 - The group had no additional comments or changes
- Start date of this course/cycle
 - The NRDS Content leads will take this offline and review the standard, and how it differs from the element used.
- Verbatim term (derived)
 - Vanitha: You see two different texts because there is one in AE form and there is one in the late AE form. It is the same CDE but a different form. You need to add one more text to include the Verbatim term.
 - o Peter: Where is this being derived from?
 - Alliance: We hide that field from the CRAs on our AE form because it is not required on every form (just the SAE form).
 - o Peter: We restrict this element to 30 characters
 - The group agreed to reformat the spreadsheet so there is only one question text per form. This will be done by the curator, Gwen Deen.

Open Forum

- Dan: Is there an availability to have standard alt text?
 - Dianne: We agreed as a group to standardize the text for all of us rather than giving the option for using alternate text.

- Derived Meaning
 - Katie: Previously we have put the text derived in italics because it is just a note, or instructional text; we do not make it a part of the question text. We do not believe it should be in caDSR.
 - o Dan: What does derived mean?
 - Katie: It is derived from a custom function, the element is text restricted
 - The group agreed that when derived is used, the words would be used in RAVE but it will not go into caDSR as part of the actual question text. The question text in caDSR should be more agnostic, not customized to the application being used to collect the data.
- Angela: When can the field label be different in Rave from caDSR? When those don't map up, what sort of differences are allowed? There will likely be other examples like this moving forward.
 - Dianne: We may need a different kind of question text, a preferred text for this initiative.
- Smita: If you are reviewing and coming back with a different CDE, how will it impact you?
 - Katie: You just have to go into Rave and update the field name; the OID is the only real link between the two. You can register an alternate OID. If you are not using the Object Form Builder and you are making them from scratch, you can make your own OID.
- Vanitha: Can we get a copy of the forms in a word document?
 Neesha: Yes, we should hopefully have it by the next meeting

Next Steps

• Continue reviewing the Adverse Event Forms

P.

Attendance:

Name	Affiliation
Katie Allen Ziegler	Alliance
Gisele Sarosy	СССТ
Dan Jameson	COG
Smita Subramanian	COG
Wendy Wong	COG
Ginger Riley	CTSU
Mary Vienneau	ECO-ACRIN
Christina Warmington	Essex Management
Neesha Desai	Essex Management
Andrea Denicoff	NCI
Dianne Reeves	NCI
Gwen Deen	NCI
Vanita Patel	NRG
Vanitha Chockalingam	CTSU
Angela Smith	SWOG
Cathy Rankin	SWOG
Peter Clark	Theradex