

NRDS Content Working Group
Tuesday June 30, 2015
Meeting Minutes

| Action Item | Who | By When |
|---|---------------|---------|
| Post revised spreadsheet to wiki | Neesha Desai | 7/7/15 |
| Send out meeting minutes | Neesha Desai | 7/7/15 |
| Work with Vanitha to get the screen shots that show the instructional text for the check boxes | Neesha Desai | 7/7/15 |
| Change Date first Learned to Date of CDMS data entry. Work with CTEP to determine if this is possible | Dianne Reeves | 7/15/15 |

Agenda Topics

Meeting Recap – Neesha Desai welcomed the callers to the meeting and provided a brief recap from the last meeting.

Adverse Event Questions Forms

- CDE 3125300 –
 - Dianne: Last time we discussed having a small set of alternate question text that could go along with the CDE that people could use based on modality. If you are using “visit” you would be able to use start date of this intervention, treatment, etc. but it would all point back to the same CDE. Would that work for everyone?
 - Peter: I think that is an excellent idea. The CDE would have several alternate text that could be used based on the modality.
 - Tina: Yes
 - Cathy: Yes
 - Rebecca: We would
 - Dianne: Is there anyone that cannot use this?
 - No members responded.
 - **Decision** – Alternate question text will be used and in this case a small number of alternate texts that are primarily modality-specific (imaging, surgery, drugs, radiation therapy, etc.) will be approved.
- CDE 2744943 – Course/Cycle
 - Peter: Can we use the alternate question text for this too?
 - Dianne: You were going to add course cycle as instructional text; we could but only Theradex requested this.
 - Tina: If we were to allow the groups to use the same text on the forms, then that would make sense.
 - Dianne: We need to ensure that all items that have this issue (course and cycle) will be formatted the same.
 - **Decision:** We will come up with an alternate text and use it for all areas with the Course/Cycle / Alternate question text will be used. So only an approved number of alternate text questions will be approved by this content group.
- CDE 3125301 – Adverse Event Term
 - Tina: The question text is wrong and we believe the wrong CDE has been used.

- Peter: In the current integration only the term is shown but in the background, you get the term and the code.
 - Vanitha: This will display the AE term; column A (in tab 3125301) is the MedDRA code and the user string (caDSR) that is used, we have created a custom table with this content.
 - Peter: Technically the question text is wrong but it is what the user wants to see. We should keep the question text the same.
- **Decision:** We will keep the same question text.
- CDE 3131334 –
 - Brenda: Would you be subsetting a list of these to get the SOC codes?
 - Dianne: What are you choosing from that list? What are you looking at when you make a choice, term or code?
 - Peter: It is a derived term, there is nothing to choose
 - **Decision:** This section it derived, so we don't really need a CDE to describe it.
- CDE 4359260 - Adverse Event Evaluated this cycle
 - Peter: What does evaluated mean?
 - Katie: It shows when/if the AE has been experienced. If it was evaluated, it could still be a grade 0, because this would be a solicited Adverse Events.
 - Vanitha: Would this be a core question? Theradex does not have the listed AEs. We use two dictionaries to derive the form when the form is launched. They have to select the AE from the dropdown list on the AE question.
 - Peter: We are planning to hide this field because it is always yes and is extraneous data.
 - Vanitha: If it is an unsolicited AE, it will always be yes.
 - Shauna: We still ask the question
 - Vanitha: We have the choice to keep it in and just hide it.
 - Dianne: If we need a CDE that asked if it was evaluated, we need to find a better CDE.
 - Vanitha: The field OID is the name of the CDE, what will we do if the field name changes? I do not want to change the OID.
 - Katie: You can request an alternate text for the OID.
 - **Decision:** Question text is correct but the CDE is wrong; we have to make sure that the OID and the field name work (continue discussions with Vanitha). We need to find the correct CDE and then work with Vanitha to apply the correct OID and text for the integration.
- 2747959 – Adverse Event (grade) grade description (first 120 characters) / 2747999 Adverse event (grade)
 - Are these the same?
 - Dianne: The definition is that it is a numeric code
 - Vanitha: The site should understand the description of the grade; when we went into the descriptions, some were over 120 characters. We decided that with up to 120 characters, the site would have enough information to choose the best option for the grade. The site will select that along with the grade and it will automatically derive based on row 15.
 - Dianne: We need to have a character display of each specific AE term grade description. The full description is row 15 and the shortened description is row 12. We need a full grade specific description. We need to find a better CDE
 - Katie: We discussed this before and decided not to curate it because of the amount of options and because this is a derived item.
 - **Decision:** CDE 2747999 derived, no changes needed.

- CDE 2944515 Hidden / CDE 2944545
 - Dianne: Do we have an agreement that there will be a 0 in this one?
 - Katie: There has to be to document the absence of an AE. This is a derived field based on line 12 (AE grade description).
 - Peter: We would not want to see Grade 0 in our list.
 - Katie: If you have solicited events, you have to have a 0 for the grade to show it was not experienced.
 - Peter: Don't we allow them to enter a number instead of picking a long definition?
 - Katie: One of the decisions was to have them select the definition; Shanda said it was a requirement to select the grade description for the CRA.
 - Vanitha: Shanda wanted the grade and the grade description, so we are providing both to the LPOs and allowing them to choose. One will be derived and hidden from the site user. The LPO can decide if they want to show it; they can just see the grade and not the grade definition if they want.
 - If you do not collect the AE, then the 0 will not be part of the code.
 - Peter: Are you doing this with a backend database or the caDSR?
 - Vanitha: The list of all of the grades is coming from a custom table, programed by Mayo. We have added the 0 via a custom function.
 - Peter: You always want to see the 0 when it is solicited, but if it is unsolicited, you don't want to see the 0.
 - Vanitha: We have that logic implemented.
 - **Decision:** Add a descriptor "The 0 is added for solicited CDEs as needed, and not per the CTCAE version 3 and 4" to ensure there is not confusion. The group agreed the coded values are how they should appear.
- 3125302 – Hidden – Duplicate from above
- 4358261 – 4358933 – Check boxes
 - Shauna: Think this causes some confusion with the sites
 - Katie: We did add text in front of these CDE (i.e. did the AE result in: etc.)
 - Peter: That is how Theradex uses it.
 - Tina: There is a screen shot with the proper text. Neesha Desai will work with Vanitha to get the screen shots that show the instructional text.
- 4358931 / 4358933 Required intervention / Other
 - Update definition for numeric code
- 4358131 – Date first learned
 - Katie: I think Rave should just add Date first entered
 - Andrea: Should we just remove this CDE? Why do we need this field?
 - Katie: They want this information to understand when it was first learned about versus when it was actually reported.
 - Peter: I think it will have to be the date of entry or when the AE happened; maybe we just include a time stamp in the background.
 - **Decision:** Change to Date of CDMS data entry. Need to review the CDE definition. This is the starting date to determine reporting type and when it will be due (although if they are delinquent it may not be correct). Still requires further discussion with CTEP.
- 3014791 – Time zone

Next Steps

- Continue reviewing the Adverse Event Forms
- Confirm instruction text in screen shots – relating to items above
- Discuss the need for CDE to describe 'Date first learned' with CTEP (Dianne)

Attendance:

| Name | Affiliation |
|----------------------|--------------------|
| Katie Allen Ziegler | Alliance |
| Shauna Hillman | Alliance |
| Gisele Sarosy | CCCT |
| Dan Jameson | COG |
| Smita Subramanian | COG |
| Vanitha Chockalingam | CTSU |
| Mary Vienneau | ECOG-ACRIN |
| Christina Warmington | Essex Management |
| Neesha Desai | Essex Management |
| Dianne Reeves | NCI |
| Andrea Denicoff | NCI |
| Rebecca Paulus | NRG |
| Sara McCartney | NRG |
| Brenda Maeske | SAIC |
| Tina Taylor | SAIC |
| Cathy Rankin | SWOG |
| Peter Clark | Theradex |
| Ginger Riley | Westat |