

**NRDS Content Working Group
Tuesday July 7, 2015
Meeting Minutes**

Action Item	Who	By When
Post revised spreadsheet to wiki	Neesha Desai	7/10/15
Send out meeting minutes	Neesha Desai	7/10/15
Touch base with Vanitha regarding schedule of the project	Neesha Desai	7/10/15

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 4358951 – Send all AEs for Evaluation (Checkbox)
 - **Decision** – No comment, approved as is
- CDE 4358954 – Report Type to be Submitted (Character field)
 - **Decision** – No comment, approved as is
- CDE 4358957 - Withdraw expedited report (Checkbox)
 - **Decision** – No comment, approved as is
- CDE 2747999 - Adverse Event Grade Description
 - Gwen: This CDE was previously used with question text of "Adverse event (grade) grade description (full description). Does anyone have an issue with this question text?"
 - **Decision** – No comment, approved as is
- CDE 2003588 - Start Date of Reporting Period – Gwen: This CDE was previously used but it was "Start date of this course/cycle"
 - Does course/cycle apply to late events?
 - Vanitha: We treat it the same as the treatment cycle; we are hiding the cycle number for the late cycle.
 - Gwen: In addition to the alternate text for course/cycle, we may need this for follow-up period. Is there any other recommendation?
 - Start date of reporting period was requested
 - **Decision:** Add "start date of reporting period" as a new alternate text.

SAE Form Prioritization – Tina presented a list of prioritized SAE forms. She noted that we reached out to some of the working group members for their input on the most logical way to review the forms. Vanitha stated that the SAE Reported Initiation and SAE Submission forms are currently changing so wait to review those.

SAE Information Form

- CDE 2179633 – Report type selected by user (derived)
 - Wendy: We have a date of onset for AE
 - Vanitha: You can add it yourself, to your own form
 - **Decision** – No comment, approved as is
- CDE 2183498 - Present Status (required if the primary AE is Yes)

- Gwen: This is not aligned with the NCI Standard. Is there any reason we would need to move to the NCI Standard for this question or stay with the current PV and meaning?
- **Decision** – No comment, approved as is
- CDE 2199512 - Primary AE, Earliest Awareness Date (derived – yes/no)
 - Gwen: Would the text yes/no or the coded value 1/2 be preferable?
 - Shauna: I thought we were going to go with the short text strings
 - Angela: I would prefer y/n but since this is a derived field, I am not sure how it would work.
 - Decision – Group agreed for a short text abbreviation for all values: Use Y/N instead of coded value 1,2.
- CDE 2744993 - Start Date (the date on which the AE was first evident)
 - **Decision** – No comment, approved as is
- CDE 2002145 - End Date (the date the AE ended)
 - Gwen: This is not the standard we typically use; what has others been using for this? Has anyone used a date for the end date?
 - Alliance, NRG, and Alliance does not use an end date.
 - Gwen: If this is used and required, I would recommend not using the Alpha DBG field, since there has been issues with Rave.
 - **Decision** – No comment, approved as is
- CDE 4358315 - Numeric code to signify whether there were AE in the reporting period?
 - Gwen: The definition will need to be updated. It currently states numeric code but since we are moving to the short text string Y/N we will need to be consistent.
 - Angela: You should be able to get the code from the type
 - **Decision** – Update definition text from numeric to text
- CDE 4358319 - *Are there laboratory results associated with any serious events occurring this reporting period?
 - **Decision** – Update definition text from numeric to text

SAE Pre-Existing Conditions

- CDE 2003874 - Specify other medical history description (if medical history is other than provide other description here)
 - Shauna: This does not make a lot of sense to me.
 - Vanitha: This is coming from the CTEP Data Dictionary; if there is another pre-existing condition that is not in the list is collected in the next element. If other is used, this field is used to describe other; look for existing and/or create new CDE with TEXT, other.
 - **Decision** – Look for existing and/or create new CDE with TEXT, other.

SAE Con Med

- CDE 2179777 - Concomitant Medication (Derived)
 - Vanitha: If they are collecting the concomitant medication in their form, it will be derived from loading the concomitant medication form. If none of the values matches their form, they will have to use the “other” selection.
 - **Decision** – Look for existing and/or create new CDE with TEXT, other

Prior Therapy

- CDE 2182486 – Prior therapy administered type[DSL]
 - Vanitha – This comes from the CTEP Database
 - **Decision** – Look for existing and/or create new CDE with TEXT, other

- CDE 3028744 and 3028746 – Start date/Stop date
 - Gwen: They are using the NCI standard for the end date of the intervention. Capitalization is an issue, which will be corrected in the style.
 - Shauna: It says intervention from the trial, is this from trial or prior therapy?
 - **Decision** – Look at the definition to see if we need a new element or if we can utilize what we have.
- CDE Agent Name (CTEP Database)
 - Gwen: This pulls out the name and the code for the drug.
 - Vanitha: We will be getting the name on the 158 and the responding code will be derived from the 159. The reason we have this as the same CDE is because the code and name will come in together and we will separate them.
 - Shauna: Can you have the same CDE have different formats/outputs?
 - Gwen: It depends on the type of CDE to start with, in caDSR, this should be a text only field. They will be pulling this from a pre-set list in CTEP, so this should be able to come through. I am not sure if this is the appropriate CDE for this because the value name is just the name of the drug.
 - **Decision** – Look at this for new CDE – existing is text only.

Laboratory Text and Results

- CDE 4331012 – Lab Test and Category
 - Gwen: This is broken out to Lab test derived and for an “other” name
 - **Decision** – Need new CDE or look for existing “other” CDE
- CDE 2192852 - Lab Category (derived)
 - Vanitha: We get this information from the CTEP database; we will get it from 127 to 130; mapped values.
 - **Decision** – Update the CDE Definition for the caAERS system
- CDE 4359896 – Lab Type
 - Tina: This definition does not make sense
 - Vanitha: This is supported currently by CTEP; if the user selects the baseline for the lab, the same record will be derived for the 3 lab types.
 - **Decision** – Review the semantics with an alternate question text
- CDE Date
 - **Decision** – No comment, approved as is
- CDE Unit of Measure
 - Gwen: Not the NCI Standard
 - Shauna: The definition does not sound like what you are after
 - **Decision** – Look into the NCI Standard

Open Forum

- Vanitha - We will need to coordinate the changes being made in this group with the changes being made at CTSU for the caAERS Integration Forms.
 - Neesha will work off line with Vanitha to address this

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
Shauna Hillman	Alliance
Gisele Sarosy	CCCT
Dan Jameson	COG
Smita Subramanian	COG
Wendy Wong	COG
Vanitha Chockalignam	CTSU
Mary Vienneau	ECOG-ACRIN
Christina Warmington	Essex Management
Neesha Desai	Essex Management
Andrea Denicoff	NCI
Gwen Dean	NCI
Rebecca Paulus	NRG
Sara McCartney	NRG
Tina Taylor	SAIC
Angela Smith	SWOG
Cathy Rankin	SWOG
Ginger Riley	CTSU