

**NRDS Content Working Group  
Tuesday July 21, 2015  
Meeting Minutes**

<b>Action Item</b>	<b>Who</b>	<b>By When</b>
Post revised spreadsheet to wiki	Neesha Desai	7/27/15
Send out meeting minutes	Neesha Desai	7/27/15

### **Agenda Topics**

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

### **Forms Review**

#### *Action Items*

- **Mix of coded values and text strings for permissible values**
  - Gwen: Will provide the working group a list of the mixed numeric and text values for them to take back to their organizations and come back with a final decision or either keep as is or make changes with reasons why.
  - Gwen: In our meeting last week, Vanitha mentioned the numeric codes are what the systems are expecting to receive so making any changes would have a large impact.
- **Unit of measure**
  - Gwen: Still working with our curation team to make sure we have everything we need for these forms included in the NCI Standard CDE as well.
- **Type of radiation administration**
  - Why are there @ signs in this CDE?
  - Vanitha: The commas are not allowed for the coded values. When we use the OCI, the system converts the comma to a double @ symbol and then uploads to Rave without any issues.
  - Decision: The group had no comments for the enumerated CDEs. No changes were recommended to the permissible values.
- **Cycle #**
  - Gwen: We will bring back alternate question text for this group to review and approve
  - Gwen showed the group what would be affected with this change
    - Start date with this cycle
    - Suggestion: Change to Intervention Occurrence Begin Date
- **AE Evaluated this cycle**
  - Gwen: We will create a new CDE with the same text but the definition will affect what the question is actually asking
- **Reporting period end date**
  - In the AE form we have the 2992 v4.0 and in the late AE form we are using the same CDE.
  - Gwen: If you are looking for the end date of the reporting period you don't want the end date of that treatment.
    - Katie: This is correct Gwen; you are no longer looking for treatment in follow up. We agreed we would not put the reporting period on the Late AE Form.

- Decision: Remove Reporting Period from the Late AE Form and make it LPO Specific question text. addition.
- Gwen: We will discuss with CTSU to ensure the changes are not a big impact on the caAERS Integration.
- Katie: Are we changing up the entire CRF packet or just the CDEs,
- Gwen: We are cleaning up all of the content.

### *SAE Reporting Period Information*

- **Was there an agent intervention administered on this protocol?**
  - **Decision:** No comment
  - Katie: Suggest that we modify and change the underlining and bolding
- **\* Was there a device intervention administered on this protocol?**
  - **Decision:** No comment
- **\* Was there a radiation intervention administered on this protocol?**
  - **Decision:** No comment
- **\* Was there a surgical intervention administered on this protocol?**
  - **Decision:** No comment
- **Was an investigational agent(s) administered on this protocol?**
  - **Decision:** No comment
- **Agent Name [Code][Type][IND holder][DSL]**
  - Gwen: This CDE is being pulled from CTEP Databases so we will not be touching these fields. All the information has been pulled out then split up by name, type, code and IND holder. We will not create a CDE for it.
- **Lot # (if known) – Entered as free text**
  - **Decision:** No comment
- **Total dose administered (this course/cycle or reporting period)**
  - Gwen: I pulled the duplicated from all the forms in the SAE forms. It is used as the total dose for “this course cycle” but later it’s used as total dose to date
  - Katie: Those are separate requirements.
  - **Decision:** Keep as is
- **Units of measure [DSL]**
  - Katie – Vanitha, are you pulling it from the DSE or pulling it from CTEP LOV?
    - Vanitha: We are pulling it from CTEP LOV. Even though it is derived it is to get collected and sent to FDA.
    - Katie: When you update the CTEP LOV you are going to update the CDE in the caDSR?
    - Gwen: There is no CDE for this in the caDSR so it wouldn’t complicate the other issue.
  - **Decision:** No changes needed.
- **Delay:**
  - Gwen: This is a text term to delay an administration of an agent with a Yes/No coded value field.
  - **Decision:** Will need to reconcile the definition or how it’s being used.
- **Duration Delay**
  - **Decision:** No comment
- **Delay Unit of Measure**

- **Decision:** No comment
- **Dose Modifications**
  - **Decision:** No comment
- **Manufacture name (name of the company that manufactured the device).**
  - **Decision:** No comment
- **Manufacture City**
  - **Decision:** Make the definition human readable.
- **Manufacturer state/province - Not a human readable definition**
  - **Decision:** Make the definition human readable.
- **Device operator (person who uses the device)**
  - **Decision:** Edit the enumerated Values
- **Total Dose (to date)**
  - Gwen: This may not be the appropriate CDE since you are looking for total not during a cycle or course.
  - Peter Clark: It sounds like a different concept.
  - **Decision:** These are two different CDEs. Gwen will check the caDSR to see if there is a match.
- **Scheduled number of fractions (planned number of radiation sessions)**
  - Gwen: The concept does not include planned; a total number of fractions
  - Rebecca: If we are collecting data related to something that is going to happen the site may not deliver all the fractions that is why is says planned.
  - Vanitha: The data points that are added to this are based on what is being collected for the radiation therapy protocols, all the data points are needed for this form, but changing the CDE if it is not making sense that is fine.
  - Rebecca: What triggers the completion of the form?
  - Vanitha: If an SAE occurs they have to enter values in the required fields.
  - Rebecca: If the protocol was requiring 35 fractions of radiation therapy and the protocol therapy occurred at 28 this makes sense.
  - **Decision:** Address “planned” as we may need another CDE.

### *Open Forum*

- Angela: I am confused on what is bearing our decision today about these codes. What affect that will make on decisions going forwarded? We have made a decision about text and codes but if we wanted to use dose modifications on another form would we be able to change it? All the Yes Now that are 1, 2 in the integration, can we use Y/N for different forms?
  - Tina: What we are going to do is providing everyone a list of the coded PVs whether numeric or text and you take it to your groups and let us know what your feedback and input would be.
  - Katie: What is the plan with all the CDEs that have 1 and 2, are they going to have new CDEs? Is this just for the integration or is it larger than that?
  - Gwen: They have not been recreated with the true 1 and 2. Some are coded.
  - Katie: I know you can't touch the 1 and 2 for caAERS but are we creating a new CDE with the 1 and 2 in terms of changing the caDSR?
  - Gwen: We can address this with our upcoming meeting with CTSU.
  - Angela: I do not want to be stuck with 1 and 2 and I want my Y and N for other forms.
  - Neesha: We will take this back to NCI Leadership to additional confirmation.

- Katie: How will the style guide be added into this?
  - Gwen: I have been collecting comments and feedback to create the style guide as we discuss the CDEs in the meeting. I can provide a list of what those recommendations are so far.

### Next Steps

- Continue reviewing the Adverse Event Forms
- Discuss the style guide

### Attendance:

Name	Affiliation
Katie Allen Ziegler	Alliance
Vanitha Chockalignam	CTSU
Mary Vienneau	ECOG-ACRIN
Neesha Desai	Essex Management
Gwen Dean	NCI
Andrea Denicoff	NCI
Rebecca Paulus	NRG
Tina Taylor	SAIC
Angela Smith	SWOG
Cathy Rankin	SWOG
Peter Clark	Theradex