**NATIONAL CANCER INSTITUTE**

**NRDS Content Working Group**
**Tuesday July 28, 2015**
**Meeting Minutes**

| Action Item | Who | By When |
|---|---|---|
| Post revised spreadsheet to Wiki | Neesha Desai | 8/3/15 |
| Send out meeting minutes | Neesha Desai | 8/3/15 |

## Agenda Topics

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

**NRDS Content Working Group Goals/Objectives** – Dianne discussed the NRDS Content Working Group goals and objectives.

- Dianne: When these standardized CDEs from the caAERS Integration will be used in other forms, what attributes would people want to change?
- Angela: For variables that share dictionaries in Rave, they need have to use the same codes. If one element uses yes/no and another element will use 1/2 we will run into an issue; are we allowed to create separate dictionaries for non-standardized elements?
  - Dianne: So it is not a question about variable-by-variable, but a set of variables that share the same dictionary?
  - Angela: Yes. I don't know any other attributes we should be considering, but the Yes/No versus 1/2 is one that stands out.
- Peter: There is sometimes alternate question text that will allow for additional flexibility. I would think the use of the CDEs on other forms should not be restricted to our decisions here. Maybe we want to restrict these CDEs to be only used on the standardized forms.
  - Dianne: So the approval of this set of variables would be very form specific, and we should record them that way? We would need to ensure it is very clearly stated that it is recommended only for these sets, and that coded values (PVs) and question text would be more granular than usual, for a specific form.
- Angela: Another example, if the format of a standardized field is decided to be a numeric value and you want to use that variable with a different format (with a different decimal or length), those types of things are shared in Rave because they are variables used across forms. If we make decisions about the standardized variables, we will need to make recommendations about non-standardized elements.
  - Shauna: What is the value of governance for non-standardized variables?
  - Angela: Not that we would be governing these, but it will require two dictionaries (one with yes/no and one with 1/2).
  - Dianne: Is that the way we way to implement these, with two dictionaries?
  - Angela: That is not the way we would hope to do it.
  - Shauna: Don't we want the integration to go with our recommended standard?
  - Dianne: If our group agrees to a set of variables that would require changes to the integration, we plan to move this forward with clear and strong reasons for making the changes. At the start of this work it was emphasized that changes should be minimized and made only when really needed.
  - Angela: It is not acceptable to use two different dictionaries in Rave, this needs to be weighed with the integrations.

- Ginger: I agree, we are supposed to focus on the content that should be used across all the LPOs, and if changes are needed those recommendations need to go forward.
  - Angela: If our job is to say what is ideal, and that either gets approved or shot down that was not what I thought was happening last week. I think we need to revisit that.
  - Dianne: We need to send strong reasons with why we are or are not making recommendations to change items. The bottom line, we want to focus on what makes the most sense. And the integration team needs for our changes to be batched.

- Shauna: It doesn't make sense to have the Yes/No encoded in two different ways on the same form.
  - Dianne: Remember that we are retrofitting with CDEs that were created over the years and were not all created specifically for one form. If we are using a 1/2 dictionary to code Yes/No and others are using Y/N, that can be done if needed.
  - Shauna: I think we need to switch it to Y/N, instead of 1s and 2s

- Peter: I think the way Rave re-uses dictionaries, within the standardized forms; we should definitely have the most logical and user friendly coding available but when the CDEs are used in other forms, there needs to be more flexibility (or use other CDEs).
- Angela: The overall thing I am proposing is to use Y/N instead of 1/2 or yes/No.
- Decision:  Bring this up at the next meeting to make sure the LPOs are in agreement before these changes are made.

## SAE Forms Review

### *SAE Protocol Radiation and Intervention Form*

- **CDE 61465 - Scheduled number of fractions (planned number of radiation sessions)**
  - Rebecca: The only way this makes sense if it is the number of fractions already delivered (actual delivered, not planned)
  - **Decision:** This is the actual fractions delivered, not the planned number.

- **CDE 218056 – Number of elapsed days (number of days that therapy has not been performed due to Adverse event)**
  - Rebecca: The text in parenthesis makes no sense for what this is.  The elapsed days is usually the time span over which the radiation is delivered but here it is the amount of therapy not done because of an adverse event.  It should not be a lapse, it should be time delayed maybe)
  - Gwen: This was added by Vanitha, it was not in the system
  - Vanitha: This particular field needs to be entered if it is a radiation intervention; this is the number of elapsed days.
  - **Decision** – Vanitha will go back and change the wording in parentheses.

- **CDE 2192839 - Adjustment**
  - Rebecca: The inclusion of drug withdrawn concerns me; I think it means early termination of radiation.
  - **Decision** – This CDE appears on the SAE Protocol Radiation Intervention form although Radiation therapy does not use the permissible value "drug withdrawn".  It should be early termination of radiation. Need to discuss the modality

- **CDE 2003301 - Study Participant Identifier**
  - **Decision** – No Additional Comments

- **CDE 2003315 - Baseline performance status (ECOG/Zubrod scale) (derived if collected)**
  - **Decision** – No Additional Comments

- **CDE 2179643 - * Height (derived)**
  - Dianne: When something is being derived, do we approve this as part of the standards?
  - Vanitha: The Height and Weight are entered in the vital signs form, we are deriving it. We are allowing the user to enter into the form if it is not derived.
  - Dianne: So, we will not worry about standardizing these that are derived from other forms?
  - Shauna: We discussed that it may not be worth trying to standardize these but this is a different issue because it can be entered
  - **Decision:** Come back and review these fields. Ask Vanitha for the list of forms and data elements from which the derived elements were pulled. .

- **CDE 2179689 – * Weight (derived)**
  - **Decision:** Come back and review

- **CDE 2186204 – * Disease name (derived)**
  - **Decision:** Come back and review

- **CDE 2201858 – (If Solid tumor, NOS or Hematopoietic malignancy, NOS), other disease name**
  - **Decision** – No Additional Comments

- **CDE 3914972 – * Primary disease site**
  - Dianne: Will there be an issue with the hyphens?
  - Gwen: There should be no issues with the hyphens, it is more an issue with commas and semi-colons
  - Gwen: We should consider human readable definition
  - Decision – Create a new definition from this CDE since commas and semicolons cause issues with permissible values.

- **CDE 3914972 – (If other), other primary disease site**
  - This is a SNOMED item by definition.
  - Peter: In the target system, is there a separate field for this other primary disease or does this other value get loaded into the same field?
  - Vanitha: There are different fields in addition to the primary disease site.
  - Peter: We cannot use the other, specify in Rave?
  - Vanitha: If it is NOS, it will ask for other.
  - Dianne: Other is not in the first list but it is a separate question.
  - Decision – Need another CDE to use like the group did with Metastatic disease questions. The Metastatic CDE uses the same value domain as the Primary Disease Site question

- **CDE 62667 – Date of initial diagnosis ( If known)**
  - **Decision** – No Additional Comments

- **CDE 4359912 – Site of Metastatic Disease (Required only if Metastatic Disease exists)**
  - Gwen: This list is the same ones we saw for Site for Primary Disease
  - Rebecca: What does the site report if they have more than one disease?
  - Vanitha; It is a log line; they can add more than one value if needed.
  - **Decision** – No Additional Comments

- **CDE 3854448 – Autopsy Report?**
  - **Decision** – Change to Y/N

- **CDE 4406951 – Consults?**
  - **Decision** – Change to Y/N

- **CDE 2919255 – Discharge Summary?**
  - **Decision** – Change to Y/N

- **CDE 2179675 – Summary report sent to IRB?**
  - **Decision** – Change to Y/N

- **CDE 4359874 – Other Information?**
  - **Decision** – No Additional Comments

- **CDE 2201044 – (If yes) specify other information**
  - **Decision** – No Additional Comments

- **CDE 2201348 – Are there any other contributing causes?**
  - Gwen: The CDE for this may be incorrect.
  - Vanitha: Please send me this and I will look into it
  - **Decision** – Vanitha look into this; if this is wrong, another will be provided.

- **CDE 2192939 – Other contributing causes**
  - **Decision** – No Additional Comments

- **CDE 2199908 – Serious? (derived)**
  - **Decision** – Change to Y/N

- **CDE 3134585 – Select treating physician name(CTEP ID)[DSL]**
  - **Decision** – No Additional Comments

- **CDE 4359972 – Select reporter name (CTEP ID)[DSL]**
  - **Decision** – No Additional Comments

- **CDE 4359977 – Additional email recipients**
  - **Decision** – No Additional Comments

- **CDE 4360156 – Checking "I certify" means that this report has been reviewed and approved by a physician or his/her medically certified designee responsible for the care of this Patient.**
  - **Decision** – No Additional Comments

- **CDE 4360159 – Select the checkbox to submit the expedited report to NCI**
  - Shauna: The definition is different from the question text; there is nothing about compliance in the definition
  - **Decision** – Check out the concepts for this CDE; insure that 'compliance' is not in the concepts. The question text, definition and DEC concepts should all be in agreement.

### *Open Forum*

- Dianne: How long do we want for you to take the final spreadsheets back to your organizations for feedback?
  - Peter: 3 weeks
  - Ginger: I believe we have used 2 to 3 weeks.
  - Dianne: We will ask for 2 weeks and at the end of the 2 weeks, we will ask how much additional time they require.

## Next Steps

- Content Review
  - Distribute the SAE and AE before/after spreadsheet for review
  - Working group will review changes and come back with any comments/approval on behalf of their organization

- Identify a list of use cases for using the caAERS Integration CDEs on other forms
- Review style guide and provide feedback to neesha.desai@nih.gov
  - Will be posted on wiki this week and an email will be sent out
- NCI Leadership planned discussion
  - Discuss the use cases provided by this group to determine if the standardization applies only to the caAERS integration forms or anytime the CDEs are used on any forms.
  - Discuss implementation approach and timelines

## Attendance:

| Name | Affiliation |
|---|---|
| Shauna Hillman | Alliance |
| Thalia Beeles | COG |
| Wendy Wong | COG |
| Vanitha Chockalignam | CTSU |
| Ginger Riley | CTSU |
| Mary Vienneau | ECOG-ACRIN |
| Neesha Desai | Essex Management |
| Christina Warmington | Essex Management |
| Gwen Dean | NCI |
| Dianne Reeves | NCI |
| Rebecca Paulus | NRG |
| Vanita Patel | NRG |
| Tina Taylor | SAIC |
| Angela Smith | SWOG |
| Peter Clark | Theradex |