NIH **NATIONAL CANCER INSTITUTE**

NRDS Content Working Group
Tuesday September 15, 2015
Meeting Minutes

Agenda Topics

General Comments

- Gwen: We will not be changing any coding for CDUS coded permissible values; we cannot make changes to those.
- Gwen: Instead of using the single letters of Y (Yes) and N (No), we should discuss using Yes, No, and Unknown written out because the words are so small.
- PV – 0-100 and the PV meanings are the descriptors. Does anyone have any other suggestions for this section?
  - Peter Clark: At Theradex we have found the descriptions are very important but the end users do not always have these descriptions memorized and/or it is sometimes not available on a source document. What we have done, we have a CDE in which the PV meaning has the code, an equal sign, and the PV meaning. This provides a description and the code for the user to use. It does not come up that often but with Karnofsky, it makes a lot of sense.
  - Shauna: Would anyone be interested in just the code? So the user just selects the code instead of the long description?
  - Gwen: We have a meeting with CTSU to discuss the option of using either the code or the PV meaning, you would be able to use the permissible value as the string. If we can use the PV meaning, we could concatenate.
  - With this assumption, Peter and Shauna will support this option. No other comments were made.

AE Form Comments – Gwen Deen reviewed the feedback from the AE Forms.

- Treatment Assignment description (derived) other. We are looking to get a use case for when this event would occur.
  - Judi: If the agent was not an agent of the NCI; you might have one agent as NCI and the other one isn't.

- Yes/No Pending – None of this is being used in CDUS reporting. Will this be a single letter abbreviation or the Yes/No?
  - Gwen: The committee suggestion is to keep the words written, Yes, No, Unknown, Pending. There were suggestions to keep anything that was a shorter length of text to keep it as whole. It was brought up multiple times, so we are re-addressing it.
  - Shauna: The Alliance made this suggestion. The Y/N is clear but when you add in U and P, it gets confusing.
  - There were no comments against the option to use the words written out.

- Adverse Event (grade) grade description
  - Gwen: The change in question text was approved, other than the questioning of the duplicate word. It was suggested to remove the duplicate word.
  - Vanitha: The reason grade is duplicated because of the DSL CTEP List. The user will need to select a value from the DSL, the DSL list shows how the label will look. We have the label like that so the use will see the value in the drop-down.

- Relation of the casualty between the treatment modality and the specific adverse event.
  - It was a unanimous decision not to change the coding.

- Check box questions – These are checkboxes, which is why they are notation in the description
- Date first learned – This will be removed from the forms, we are not using the CDE. In CTEP it was used in the past and is no longer applicable.
  - ○ Shauna: Does that mean we no longer need it for SAE reporting?
    - ▪ Gwen: This is a derived field; it does not mean what it was used for.
  - ○ Peter: Does that mean there is going to be an onset date instead?
    - ▪ Gwen: I know that was an issue you brought up in some of your comments. I sent an email notification to Vanitha to request additional information. She noted that it is not required for AE reporting, just for SAE reporting. The group of elements on our list are the bare minimum. You can add start and resolution dates to your form, but these are the ones that must be included.
    - ▪ Peter: We do that but I was requesting we consider adding them to the standard form because it is part of the CDR to have those fields. If they were available, it would make mapping easier. Maybe not all studies would opt to use them but if it was available as part of the form, it would make things easier.
    - ▪ Cathy: If there is no scientific rationale for receiving this data, it doesn't make sense to use them.
    - ▪ Group agreed.
- Late Adverse Event – Reporting period is the appropriate alternate text for this form.

SAE Form Comments – Gwen Deen reviewed the feedback from the SAE Forms.

- It was suggested to turn brackets into parenthesis – no one was against
- Present status (required if primary AE is Yes) - No changes to codes because it could potentially be used in Rave with the logical order, if necessary.
  - ○ Group: There is no need for ordering in this CDE, no change to code. It does not have to do with the ordered ranking, we can leave these as a text string.
  - ○ Peter: This seems like a long string, I would go back to the numeric.
  - ○ Shauna: I thought we were not going to use numeric codes, unless there is an obvious ordering of them.
  - ○ Peter, Cathy, Shauna – agree
  - ○ Gwen: We can work offline to find a solution, possible abbreviation of this.
- Medical History (Brackets)
- Baseline recovery Nadr – approved changes to question text, no change to permissible values because they are short words
- Unit of Measure – we will be aligning this with the current list of UCUM CDE
- HTML Tags for underlining – the text was approved but the permissible values will remain because they are short words. We will not be including HTML tags for the bolded text here (and in the entire series)
- SAE Protocol Agent Intervention - No true order for this element. No need for this.
  - ○ If you read the descriptions and they have an obvious order it makes sense but this is not in a logical order right now; we should not be stuck with this moving forward. We could put it in order but it may not make sense.
  - ○ Angela: I think the order is apparent in this case.
- Delay Unit of Measure – the text and definition will be used as is because the terms are short.
- Devise operator is being pulled from DSL list from CTEP; we cannot alter this.
- Type of radiation administration – recommendation is to remove commas from the permissible values

- The type of agent dose modification – not an ordered set of PV
- Attribution – will require local ordering, will remain as numeric
- Resolve Date – Peter: There is a requirement to have a resolve date for SAEs, if we will have to enter it into the SAE form, there should be a CDE for it.
  - Gwen: I would like to chat with Dianne again before I can weigh in on this. I do want to discuss this with her and we can bring this back to you.

Style Guide Form Comments – Gwen Deen reviewed the feedback from the Style Guide.

- Capitalization – If you are curating a CDE and you are manually entering a PV, we recommend you capitalize the first letter of the first word. We would like to advise against all upper case. Proper nouns should be capitalized as well. If the permissible value comes from EDS, we cannot change it.
- Numeric/text abbreviations – We are still unsure how everyone would like to move forward when there is no standardized abbreviation for certain long terms (i.e. anatomic site).
  - Cathy: Sometimes there is not an obvious abbreviation but you must pick the most intuitive option. It is more of an art than a science. If we would like to pursue this, I am comfortable with someone providing options for this. I will be happy to help.
- Symbols/special character usage – It is recommendation to remove commas and semicolons because it causes issues with OCI.
  - Shauna: Are these recommendations for curation? What if we are not using the OCI?
  - Gwen: For those groups that use OCI, would you be willing to work on your own CDEs. I am not saying you cannot use it, but we certainly recommend you do not.
- Symbols – It is also recommended to write out the greater than and less than instead of symbols for the definitions. For those using OCI, it is an issue.
  - Judi: Have we made sure the OCI cannot be fixed to get around this?
  - Dan: It is not the OCI itself, I think it is in the core programming of Rave itself. They would have to do major revisions to Rave to add these characters.
  - Ginger: Dan is correct, that functionality was added into the OCI but based on feedback for Rave activity.
  - Katie: We do regularly use it in our label but we use a SAS label.
  - Judi: When we import objects using OCI, are SAS labels used?
  - Ginger: SAS labels are not targeted.
- HTML Tags – There were no persuasive requests, so if HTML tags are used, a field name or SAS tag needs to be available. We are going to avoid those on caAERS integration
- Form Long names – there is still debate on this issue. I will bring back this information on this as it is available.

Next Steps

- One week final review
- OPEN Demography

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Attendance:

Name	Affiliation
Katie L. Allen Ziegler	Alliance
Shauna Hillman	Alliance
Dan Jameson	COG
Amanda Fournier	CTSU
Ginger Riley	CTSU
Vanitha Chockalignam	CTSU
Judi Manola	ECOG-ACRIN
Christina Warmington	Essex Management
Neesha Desai	Essex Management
Andrea Denicoff	NCI
Gwen Dean	NCI
Rebecca Paulus	NRG
Vanita Patel	NRG
Tina Taylor	SAIC
Angela Smith	SWOG
Cathy Rankin	SWOG
Peter Clark	Theradex