NRDS Content Working Group
Tuesday June 23, 2015
Meeting Minutes

Action Item	Who	By When
Post revised spreadsheet to wiki	Neesha Desai	6/26/15
Send out meeting minutes	Neesha Desai	6/26/15

Agenda Topics

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

Standardization Strategy – Tina reviewed the NRDS Content Strategy with the group. She asked the group if they prefer finishing the content review and formatting of first the 4AE forms one by one, or doing the formatting review after the content review has been completed for all the caAERS forms. (Note: formatting review to be done using a style sheet for consistency of question text, values, punctuation, and the presentation of the content.)

- Peter: We should do it as we go along and make the alterations as we go but I am fine with doing it as a chunk if the rest of the group would like to.
- Shauna: I think we should do a chunk because if we do one each separately, it will show that we did it separately.
- Cathy: I agree, we should format all the forms at one time.
- No one in the working group opposed to formatting all the forms after the content review is completed.
- Decision: We will review the content of all four AE forms first, and then to a review of the format of each item on the four forms.

Adverse Event Questions Forms

- CDE 2992 – Reporting period end date (optional, user entered if known) or CDE 2006851 – Adverse Event Final Assessment – which CDE meets the integration needs?
  - Dianne: The reporting period could end before the AE has been resolved.
  - Katie: This is the last date that patient was assessed during the reporting period.
  - Vanitha: Have you reviewed this against the NCI Standard Form?
    - Dianne: We are checking it but we want to ensure we are working along with the integration. We will still need to assess the impact to see if a recommendation to change the CDE is needed, or if a standard CRF element would work.
  - Katie: It is when they were assessed versus when the treatment ended. If you assess the event on day 26 but the patient is still receiving treatment until day 28, what do you do?
    - Smita: Anything that happens to the patient within the whole 28 days should be reported.
    - Katie: It is the concepts behind the question, it should be the same date but it might not be.
    - Chad: Sometimes a patient will be assessed before the end of the reporting period.
    - Dianne: Rarely do the two dates coincide. The cycle dates are imposed by the treatment plan, and the reporting dates are not.

- Chad: We do not ask the date the AEs were assessed. We explain in the protocol that you should assess the AEs at the end of the cycle. We ask for the end of cycle date. Someone made a comment that this is a little redundant and I would agree with that, based on our model.
- Katie: I vote to remove this, you can just take the next cycle date and subtract one date.
  - Shauna: I agree
  - Rebecca: I agree
  - Katie: It's on the form but it's optional, and only Alliance uses it. So we should just remove it.
  - Cathy: SWOG uses this as well and it is problematic.
  - Dianne: That information should make us realize that this question is confusing for more than just our workgroup.
  - Decision: Eliminate this item in the integration, and both CDEs under consideration are not needed..

- CDE 686 - Start date of first course/cycle
  - Katie: This was needed for caAERS integration
  - Peter: It was decided that course was the proper terminology for studies a long time ago, everyone else uses cycle.
  - Dianne: What would be the detriment if we use cycle?
    - Peter: We refer to course in many other forms and have defined all of our data in the terms of course. Therefore, there would be a problem with coherency with our historical data. If we just kept it as course, I could put an instructional text on the special AE forms to note that even though it says cycle, it means course. For us, with a course you can have one or more cycles but it is the period in which we are doing our reporting, which could be and usually is, one cycle of treatment but it could be more than one. Diana Vulih (Theradex) is our manager for the clinical side of CTMS Data Management and would have a better definition of when to require a new course. We can have the same drug over multiple cycles but if there is a new drug, it would likely be a new course.
  - Smita: We use a Reporting Period, so cycle and course means the same to us. You can have multiple cycles/courses in each reporting period.
    - Dianne: We had a series of small harmonization workgroups a few months ago. In one of those we defined cycle as being a subset of a course of therapy; one or more cycles make up a course.
  - Gwen: If we are talking about these as different aspects but treating them the same, shouldn't we have a term to encase them all, like reporting period?
    - Smita: It sounds good to me
  - Rebecca: This only applies to AEs during an active treatment. How do we handle radiation therapy only trials where course/cycle number is not necessarily relevant?
  - Tina: Do we know what this is in caAERS?
    - Katie: caAERS does not differentiate, is this out of scope, we cannot ask caAERS to update their forms can we?
    - Dianne: We can, but we would need to make a case for it if you guys feel it is needed.
    - Rebecca: It is frustrating, because most of cancer research is geared toward drug therapy but it is understandable.
  - Dianne: Intervention could be better, instead of course/cycle. Some of the standard CRF CDEs use the term 'intervention'
    - Tina: A course cycle, could that be an intervention?

- Shauna: Maybe Reporting Period Start Date makes more sense to me. If you started drug A on Jan 1, you do not want the same date each time. I think the start date of the report period makes sense, however they are chunking up their visits/reporting period makes sense.
- Peter: Row 4 says first start date of first course/cycle, will that change because of this type of change? In Theradex, we enter a course number and a date for the start of the course
  - Shauna: Yes, we do that too, a cycle/visit number.
  - Katie: Cancer Control trials use visit and others use cycle. But we agreed a long time ago to just use 2072 (CDE for cycle)
- Shauna: If we can agree on something that works the most generically but it may be very vague for those that need to fill it out.
  - Peter: We can add explainers to the questions but yes, but then it would come down to a bad user interface.
  - Katie: There is checks that are looking for this verbiage and if it is changed, there will be more work around for it.
- Dan: The concept of some sort of thing done to a patient (drug or whatever), what if there was a form and the same set of data elements but different alt text based on the different modalities, so the OIDs remain the same but the sites can get the modality specific alternate text.
  - Peter: Sounds like a great idea
  - Tina: We have discussed this
  - Dianne: We will need to discuss using a set of standards with preferred question text for different modalities.
  - Decision: Explore the possibility of creating a set of data elements that may need different question text depending on the modality (radiation, drugs, surgery, gene therapy, etc.). This item is in the 'Parking Lot' for now.

- CDE 3125302 - Adverse Event Term (CTCAE v4.0) (derived)
  - Gwen: They are combining the MedDRA code plus the actual text
  - Katie: I think there is a difference between the coded value and the text string in Rave
  - Dianne: For the user string, do you need both the MedDRA Code and the term to understand what it is?
    - Peter: I think it is more user friendly and likely to avoid error (and supports searching)
    - Katie: According the data dictionary, they are not together; there is only the user string there.
  - Decision: Locate a CDE that has the MedDRA 8-digit code for the Permissible value (PV) and the Adverse Event term as the Value meaning (user string). That will be used for this item.
- CDE 3133353 - MedDRA AE Code
  - Gwen: This is being combined with the MedDRA Code and SOC; we will need a new CDE
  - Dianne: This needs to be bundled in a change because this is wrong; correct text to reflect actual question.
  - Decision: This item appears to have the wrong question text and the wrong CDE. Review to locate the correct CDE to be used.

Open Forum

- Peter Clark: We are working on the Pilot study Theradex is going to run for this integration. We needed to add a bunch more fields to meet the needs of the CTMS

Theradex system. Will it be possible to add additional fields to meet LPOs/business operations or are we supposed to use these forms as is and change our bus ops?
  - Dan: When the standard modules were presented, there were items that were required but LPOs could add whatever they wanted to the forms
  - Dianne: I am not sure if we are still working with this model. Are we?
  - Dan: I do not see how we could not go with it; LPOs will ask different questions and requiring all of the LPOs to ask the same questions does not seem right. They may need to have different questions to meet their business needs.
  - Gisele: Could the questions be optional? So each LPO could pick the questions that make sense?
  - Katie: For these elements, they are the minimum required. Any LPO questions would be more of a study build.
  - Katie: You will not be able to modify the questions/answers from the core but you will be able to add additional fields.
  - Decision: the content that we agree upon will be the required core set of fields on each form, formatted as we agree. No changes will be made to this set of fields, but more items can be added to a form as needed.
- Peter: What does the SOC stand for?
  - Dianne: The 790 terms are under different categories (SOC – system organ class, like Gastrointestinal, Dermatologic, etc..) where the individual AE terms fit under. The SOC comes from the MedDRA structure, and all the AE terms can be rolled up under these higher level categories.

Next Steps

- Continue reviewing the Adverse Event Forms

Attendance:

Name	Affiliation
Sara McCartney	RTOG
Katie Allen Ziegler	Alliance
Shauna Hillman	Alliance
Gisele Sarosy	CCCT
Dan Jameson	COG
Smita Subramanian	COG
Wendy Wong	COG
Thalia Beeles	COG
Vanitha Chockalingam	CTSU
Mary Vienneau	ECO-ACRIN
Tina Taylor	SAIC
Christina Warmington	Essex Management
Neesha Desai	Essex Management
Dianne Reeves	NCI
Gwen Deen	NCI
Chad Winch	NCIC
Vanita Patel	NRG
Rebecca Paulus	NRG
Angela Smith	SWOG
Cathy Rankin	SWOG
Peter Clark	Theradex