

**NRDS Content Working Group
Tuesday July 14, 2015
Meeting Minutes**

Action Item	Who	By When
Discuss open action items with leadership	Dianne Reeves	7/16/15
Post revised spreadsheet to wiki	Neesha Desai	7/17/15
Send out meeting minutes	Neesha Desai	7/20/15

Agenda Topics

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

Action Items – Gwen Deen reviewed the open actions with the group.

- **Course/Cycle Data**

- Vanitha: I think we have identified some of the time where the CDE will change, how are we going to alter the existing pilot study? Are we willing to change the existing studies?
 - Peter: The Theradex study is ready to go into production this Friday and we do not want to make any additional changes.
 - Dianne: All of these changes still need to go for review at another group and will take time to approve. We've talked about making these prospective changes based on a future date.
 - Vanitha: If it is not changing, that is fine. All of these protocols are going to stay in the old CDEs (AE forms) that are going to production this month. We need to find out how many data points are affected and we need to check with the LPOs for how they will do the change. They have to do it at one time. For the AE and Reporting evaluation forms we need to tally up the number of changes (CDE, question texts, etc.)?
 - Dianne: We will pull that together starting after this meeting
- Dianne: We hope to come up with a single set of forms; this alternate question text may cause an issue.
 - Peter: I wonder if it is still possible to consider that a form is the same from one LPO to the next if it has the same CDE public IDs and the same set of acceptable alternate question text. This would allow the form to be the same in the infrastructure but have its own particular flavor based on the LPOs. The only change would be what appears on the screen but all of the background information is the same.
 - Ginger: This answer may need to come from NCI Leadership. Mike stated that we should not use alternate text moving forward unless necessary.
 - Angela: This is hard to know/decide based on the point we are at this point. If the point is to have standard elements/text, I wonder to what extent we need to have the door open to alternates. I think that what Peter proposes is reasonable and I would be happy to keep it on the table but it is hard to make a decision based on where we are on the content.
 - Dianne: If this group wants this approach moving forward, I will be happy to bring it up tomorrow at the leadership call.

- Dan: The goal is to have the identical experience for all site users/LPOs or is it about back-end data aggregation? The alternate text would allow for the back-end data aggregation would be the same.
 - Dianne: We would like to make the front end user's experience the same as possible.
 - **Decision:** Dianne will bring this to the July 15 Leadership Call and the group will continue to discuss.
- **Lab Type Question (CDE 4359896 – Lab Type) - Does this definition makes sense; is it treatment or protocol related?**
 - Dianne: This is a mixture of terms and values.
 - Peter: Does this information get derived from other lab form data points?
 - Vanitha: Yes it does. When the first record is provided, the following date and unit of measure will be derived. In CTEP we take the Lab Name and then derive the lab type but caAERS integration takes lab type.
 - Peter: So there is some kind of mapping between the lab forms and the SAE forms.
 - Vanitha: Once the baseline is recorded it will duplicate the baseline for a primary and a secondary. Every time a baseline is added, there are two additional elements created. We ask the user to enter all of the information in the original lab form. Maybe the text does not make sense.
 - Angela: Maybe this is Lab Time Point, instead of Lab Type
 - Peter: Is there an expectation that there will be 3 values here, Baseline, Worst, & Recovery
 - Vanitha: Yes.
 - Dianne: What happens when the dates are not matched?
 - Vanitha: We have not built that, it is with the LPOs; it is not standardized across all of the LPOs. We do not know how many forms will be rolled out. We will need to analyze these.
 - Peter: So the user will need to look at the lab records and determine the baseline, the worst, and the best. This seems like an unregulated. We currently do it in Rave.
 - Vanitha: I agree.
 - Dianne: Is the definition ok?
 - Peter: I don't think Lab Text is helpful.
 - Angela: I don't think Lab Type is ideal but you can understand what you are getting at when you see the choices.
 - Peter: Suggested text: Baseline/Recovery/Nadir
 - **Decision:** Use suggested text: Baseline/Recovery/Nadir but the group will continue to think about this subject.
- **Unit of Measure**
 - Dianne: Does the list in A and B include all of the values that everyone uses?
 - Peter: That will take some research.
 - **Decision:** The smaller set of units of measure will be compared to the UCUM standard CDE, to make sure every value needed is in the larger UCUM set. That will allow us to use the UCUM standard here.

Forms Review

Laboratory and Test Forms

- **CDE 2183360 – Value**
 - **Decision** – No comment, approved as is (include 7 digits before, 5 digits after)

- **CDE 2004004 – Infectious agent test date**
 - **Decision** – No comment, approved as is
- **CDE 2201023 - Infectious agent**
 - **Decision** – No comment, approved as is
- **CDE 2669205 - Site of infection**
 - Peter: Is the word complicating necessary? It seems to restrict the usage?
 - Dianne: That is a good point.
 - **Decision** – Review the Definition (remove the word complicating if it is not part of structure of the question)

SAE Description of Event Form

- **CDE 2179687 – *Description and treatment of event(s)**
 - **Decision** – No comment, approved as is
- **CDE 2002146 – Date of recovery or death**
 - Amend to include in the caAERS system
 - **Decision** – Amend to include in the caAERS system
- **CDE 2179657 – (If fatal/died), was an autopsy performed?**
 - Peter: The use will type Y and get a yes or type an N and get a No
 - **Decision** – Changing field values to Yes, No
- **CDE 2192740 – Removed from Protocol Treatment?**
 - Rebecca: Is this field being filled out for Late AEs too?
 - Vanitha: Yes.
 - Rebecca: Then this is not appropriate for a Late AE; they would already be done with treatment.
 - Vanitha: We may be able to hide it based on the condition
 - Dianne: We can capture this under General Comments
 - **Decision** – General Comment: This will be conditional question with regard to Late Reported AE
- **CDE 23 – (If yes) date removed from protocol treatment**
 - **Decision** – No comment, approved as is
- **CDE 3105353 – *Has the subject been re-treated?**
 - **Decision** – No comment, approved as is

SAE Reporting Period Information

- **CDE 2192731 - Start date of this course/cycle (derived)**
 - Vanitha: When the late AE form is rolled out, we are deriving the last cycle number on the late AE form (which will be derived to here), even though one is not required.
 - Vanitha: Add an alternate question text for Late AE
 - **Decision** – Add an alternate question text for Late AE

Open Forum

- **Request to review the Adverse Event forms prior to finishing the other SAE forms**
 - The whole group agreed to move forward with this change.
- **The group was concerned on the definition of a form.**
 - Dianne: We should be able to aggregate data on the backend. We will try to make the front end as consistent as possible with an emphasis on aggregation. This will allow us some latitude in adding alternate question text and avoid any ambiguous.

- Dianne Reeves will take that back to leadership to discuss.
- **The group discussed how we will deliver the AE Forms for review**
 - Dianne Reeves will take that back to leadership to discuss.
- **The group discussed having to change the forms that are currently or planned for production in the caAERS integration.**
 - Dianne Reeves will take that back to leadership to discuss.

Next Steps

- Continue reviewing the Adverse Event Forms

Attendance:

Name	Affiliation
Dan Jameson	COG
Wendy Wong	COG
Ginger Riley	CTSU
Vanitha Chockalignam	CTSU
Mary Vienneau	ECOG-ACRIN
Christina Warmington	Essex Management
Neesha Desai	Essex Management
Dianne Reeves	NCI
Gwen Dean	NCI
Chad Winch	NCIC
Rebecca Paulus	NRG
Vanita Patel	NRG
Tina Taylor	SAIC
Angela Smith	SWOG
Cathy Rankin	SWOG
Peter Clark	Theradex