NATIONAL CANCER INSTITUTE

NRDS Content Working Group
Tuesday April 19, 2016
Meeting Minutes

Agenda Topics

Project Update – Neesha Desai provided an overall update and noted that we have received comments on all OPEN and CDUS Content sent out; the next step is to send each to CTSU for review. We are working with the AE Integration Content with CTSU to plan for implementation. CTSU is reviewing the SAE Integration Content.

- Wendy: Some of the data elements are not the same as we use in the Rave System for OPEN.
  - Dianne: Yes, there was a small inconsistency in the way it was implemented. The way it is in the data elements is the way it is supposed to be implemented. CTRP noticed this as well. Please use the one Rave is using.
  - Wendy: Should we obtain the Excel form for this then, the one on the Wiki has different information.
  - Wendy: I will forward you the screen shot for this, from the Rave Medidata, inside the Demography table (export from CTSU) the ALS document
  - Ginger: Did you use the ALS Document from our CTSU Website?
  - Wendy: Yes. 2001039 does not seem to be correct for our spreadsheet.
  - Gwen: 2865130 (on our spreadsheet) is pending implementation; once it is reviewed and approved, it will be implemented.

CDUS OPEN Content Review – Gwen Deen

- Off-Treatment Reason – punctuation issues have been fixed. There were additional comments.
  - Can "Other Treatment, never started" – Currently, these are the only options allowed to CDUS. This may map to #13.
  - Are groups having second thoughts about using CDUS Coding?
    - Kristina: Things like Yes, No, N/A used to have CDUS coding, but this is different coding.
    - Theradex is fine with either direction but I have gone along with all of these changes to remove codes when possible. These PV meanings are pretty long. I think it may make sense to use the established codes or something shorter for the PVs.
  - Dianne: What is it about long PVs that make it difficult?
    - Wendy: There is only a 25 Max for the characters for the PV in Rave. If the value is long, we change it into coding for these times.
    - Theradex: Is it the OCI that truncates?
    - Ginger: It is the OCI
    - Peter: Anything we can do to cause less work after the OCI would be best. It makes sense to keep the codes.
  - No Objections for keeping the code for this element; there is a 25 character max limit for the OCI. **Gwen will go back and review if this truncation will be an issue for another element.**
- Off study reason – Agreed to use coding for this element
- Participant subgroup code – All agreed to the new definition

- Is the participant eligible for inclusion on this study – All agreed to style change
  - Miriam: For CDUS, the question is has the study been in eligible.
  - **Gwen: Correct, this needs to be updated.**
- Performance status (Zubrod)
  - Dianne: We cannot just add a fifth category because it is set. The value meaning name should a be a short name and the text should be as part of the definition. We need to get this fixed from EVS. **We can work offline for this.**
- Response Evaluation Status – We have rephrased the definition based on a comment; all agreed to new change.
- Baseline Abnormalities Flag – We have rephrased the definition based on a comment; all agreed to new change.
- Prior Therapy Type – Included the MedDRA version, as requested. CTEP created additional numerical codes prior to MedDRA codes.
  - Group agreed Gwen should go back and see if there are MedDRA codes to replace these.
  - This is not a complete list of prior therapy; it is a shortened version.
- Dose Modification Code – Definition was rephrased based on requests
  - Request to add an additional value – Gwen: The ones in here are CDUS approved and accepted. We can ask if we can add a new one, but we will have to go back to CDUS to see if this will be an option. Request: Dose modification for a planned and unplanned event at the same time.
  - Dianne: Can you change this to pick all that apply instead?
  - Gwen: That is an option.
  - Melinda: This has always been an issue and in the past I have usually just report it as unplanned
  - **Gwen to research both options**
- Baseline Abnormality – I have added the set of responses from CTEP; they have all come from MedDRAv10.
  - Kristina: We are using MedDRAv12
  - **Gwen to check to see if CTEP has updated anything**
- Adverse Event Grade – The text for the value meaning comes directly from the content from EVS. Is this something we want to change? It would extend the definitions.
  - Dianne: They should come from the CTCAE
  - Gwen: We will need to change the value meaning for these; the request was to change the PV meaning to a longer version. Should we change the PV meaning?
  - The group, overall, is ok with the current PV Meaning
- Response at this assessment
  - Dianne: Should we expand this list to get raw data or roll up to these values
  - Request to expand the list.
  - Please add "Complete Response, Unconfirmed"
  - Kristina: Reporting response per patient vs. per patient cycle; I would use this different on my forms than I would for mapping.
    - Gwen: We need to find a CDE that can map the individual recordings of the status after the overall status/best response. CTEP evaluates all responses from the patients, not just one response.
    - Kristina: I feel like we would get an error if we tried to provide more than one.
    - Melinda: That was the case up until about 2 quarters ago when they made a silent change

- o Tina: It looks like some of these PV meanings may be more than 25 characters.
- Observed date – Changed the definition; all agreed to change
- Assessment Comment – All agreed to change of Question Text

Next Steps

- Next meeting is scheduled for April 26 @ 4:00 pm (ET)

Attendance:

Name	Affiliation
Kristina Laumann	Alliance
Phoebe Chang	COG
Wendy Wong	COG
Ginger Riley	CTSU
Melinda Flood	ECOG-ACRIN
Miriam Bischoff	ECOG-ACRIN
Christina Warmington	Essex Management
Neesha Desai	Essex Management
Dianne Reeves	NCI
Vanita Patel	NRG
Gwen Deen	SAIC
Tina Taylor	SAIC
Angela Smith	SWOG
Cathy Rankin	SWOG
Peter Clark	Theradex