

**NRDS Content Working Group
Tuesday September 1, 2015
Meeting Minutes**

Agenda Topics

Status Update – Neesha provided a brief overview of the Content Review Process and explained the next steps. The goal is to have the final recommendations between September 11th through Sep 18th. Neesha noted that all but one group has returned their feedback and asked if we should we wait to review all of the questions until we get feedback from all of the groups.

- Ginger: I see value in waiting so we see if there is impact from the additional comments
- Cathy: I agree.
- ****Decision:** The group agreed to wait until all comments have been provided to discuss the feedback.

Open Demography – Gwen Deen pulled out the Open Demography 8 elements; there are current data elements that are being used that are retired (red)

- Patient's Initials
 - Capitalization from the style guide
 - Peter Clark: For all of the years we have been collecting data, we have never collected the patient's initials and we believe it is a violation of HIPAA. Any patient initials we get from OPEN is blocked out to ensure we are meeting HIPAA regulations. We suggest removing this field completely from the registration process.
 - Thalia: OPEN already has a movement to remove the initials; the initials will come through as dashes.
 - Judi: We were queried about how we feel, we are not a covered entity under HIPAA and we need the patient's initials for quality of site.
 - SWOG would also like to keep the initials.
 - Ginger: They will remain being collected in OPEN but this will be confirmed in a separate confirmation to those LPOs that took part in the discussion. It is driven by the LPO feedback/comment.
 - Judi: It facilitates the communication with the sites, to ensure they are looking at the right patient.
- Patient's Date of Birth
 - Capitalization from the style guide (for the label of question text, not the output)
 - Judi: If we are changing based on the style guide, how will it impact our currently existing studies/data elements? Are these new CDEs or changes to the existing ones?
 - Gwen: It would be changes to an existing CDE unless
 - Katie: This would only be moving forward, not for existing studies
- Ethnicity
 - Peter Clark: I know we have discussed coded values before, in Theradex we use the codes for these permissible values that CDUS is expecting, so we would have to map the words to the codes. Is anyone open to keeping the numeric codes for these categories?
 - Katie: I thought we agreed that we would not touch OPEN, other than the descriptions.
 - Gwen: In OPEN, we have actual text, not code.
 - Judi/Cathy/Katie: Vote to keep as is.

- Gender of a Person (retired option)
 - Gwen: There is one that is retired and one that is active (in the caDSR). Previously, we discussed using Female, Male, Unknown, Unspecified instead of using Female Gender, Male Gender, and Unknown.
 - Neesha: CDUS takes female, male, and unknown (1, 2, 9 code)
 - Judi/Katie: I vote to change the question text of Gender of a Person to Gender
 - Peter: I think the term female gender is such a weird and awkward term; I agree to change.
 - ****Decision:** The group agreed the active meaning (female, Male, Unknown, Unspecified) should be used instead of the retired option
- Country of Residence – two letter code and the written out name of the country
 - Peter: I believe the code for “other” has continued to create an issue for Rave; there is no actual two digit code.
 - Gwen confirmed this is still an issue
 - Katie: In Rave, there is a 5 character format, so it can handle “other” so it has not been an issue.
 - Judi: Is there inconsistency in the definition?
 - Gwen: Yes, we could change the definition to include the 5 digit option of other or we could find a way to abbreviate “other”
 - Katie: I vote to just change the description
 - Peter: We can just continue to work with the current method, as in the past.
 - Katie: Turks & Caicos Islands has an issue because of the ampersand
 - Peter: We should change that.
 - Katie: There are around 5 that are this way, we can change these because they are on the user string
 - Katie: The N/S Korea countries are not consistent with their capitalization
 - ****Decision:** Update the description to note that “other” has a 5 digit option; look into removing ampersand from countries and updating the capitalization for N/S Korea.
- Zip Code
 - Capitalization to question text
 - Katie: The definition does note 5 digit but it can accommodate the extension
 - We should not include the extension to safeguard confidentiality
- Method of Payment (retired option)
 - Capitalization and ampersand issues
 - Ginger: This was retired prior to the OPEN forms being implemented; somehow this is still in there. We were not really sure how this happened, but it has always been retired.
 - Vanitha: I am surprised they have been using a retired CDE for the standardized forms.
 - Ginger: We identified this before as well. We can discuss this off-line.
 - Judi: Are there plans to incorporate ACA plans or new forms of insurance. I don’t know how the content would be populated for this?
 - Thalia: CDUS uses this
 - Judi: Would CDUS be able to accept new content?
 - Thalia: They may have us map everything to other
 - Andrea: That is a good point because of the affordable care act, I don’t know how it will be changed but healthcare has changed a lot since these were developed. I am not sure if there would be other variables. An option would be to ask Cancer Care Delivery and SWOG (Scott Ramsey) these questions. This would be a good time to visit these suggestions/changes.

- Race
 - The capitalization is pulled directly from concept, so it would not be able to be changed.

Review Comments/Feedback from Review – Gwen Deen reviewed some of the comments/feedback from the review.

- Does any group feel the need to have pictographic/paper forms?
 - Katie: Yes, it is really helpful to have these additional options for review. I can send Neesha the paper Case Report Forms we created (it will need to be updated)
- Style Guide
 - Katie: I thought the style guide was something we wanted to extend beyond this group?
 - Neesha: It can be used but it is not mandatory.
 - Judi: Anything that can be put in order should not have alpha-numeric; we may need to go softer on the guidance. Anything that has order to it should be kept in numeric code.
 - Peter: I agree
- We would suggest using a cut point for where a valid value is less than let's say 10, you write it out rather than abbreviate.
 - Katie: In Rave, we find a Yes and a No more helpful than a Y and an N. We think we should limit the length for anything under 10.
 - Judi: We said as short as possible
- caAERS_AE CRF: "Cycle", "Course", and "Visit" is used for AE question.
 - Judi: You would choose the one that most corresponds to your study?
 - Gwen: Yes, based on the research being conducted at the time.

Next Steps

- Review open issues with OPEN Demography; Gwen will bring back any discrepancies
- Kick off final review on September 11th (for one week)
- We will post the Paper CRF to the Wiki (from Alliance)

Attendance:

| Name | Affiliation |
|------------------------|--------------------|
| Katie L. Allen Ziegler | Alliance |
| Dan Jameson | COG |
| Thalia Beeles | COG |
| Wendy Wong | COG |
| 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 |
| Tina Taylor | SAIC |
| Cathy Rankin | SWOG |
| Peter Clark | Theradex |
| Amanda Fournier | Westat |