

NRDS Content Working Group
Tuesday June 9, 2015
Meeting Minutes

Action Item	Who	By When
Send out meeting minutes	Neesha Desai	6/12/15
Gwen to start mocking up a Style sheet.	Gwen Deen	6/12/15
Send Neesha a sheet that his group has already developed as a starting point	Dan Jameson	6/12/15
Send a poll, offline, to vote ensure the group all agrees with moving forward with caAERS instead of OPEN.	Neesha Desai	6/10/15

Agenda Topics

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

Integrations Matrix – Gwen Deen provided her CDE evaluation findings; she received the CDUS content yesterday and has not had the opportunity to add this information into the data.

- Enumerated has a value set
- UnCoded = There is no abbreviation/numerical code or anything to represent the actual term (text terms or strings instead of coded values)

Integration Matrix Spreadsheet

- Gwen went over a few of the issues she saw with the existing values:
 - All caps used for the value meanings in some instances
 - Ampersand in some values
 - Use of for'/' replaced by 'for' consistently
 - Abbreviations
- Gwen: I recommend we start with the enumerated value domain and make a decision of how we want to move forward with these 45 CDEs and then continue through the rest of the set.
 - Shauna: I agree, we start with this set and decide on how we will code.

caAERS Example

caAERS is fairly standard with their module (it's an integration) but it is different from the Adverse Event (AE) Module of CRF standards. They are not utilizing the standard Common Data Elements (CDEs).

- Dianne: caAERS is the one with the larger sets. Is there a set that is different from our standard ones? Are all the ones being used in caAERS released? Are there any retired ones in this set
 - Gwen: These are all released data elements; some of these are completely different CDEs from the CRF standard elements.

- NRDS_Content_Matrix.xls Key; this matrix shows which system the elements are used in
 - Red– the data does not match NCI standards
 - Green – match NCI standards
 - White – CDEs that are not present in the NCI standards, they are only used within caAERS reporting (stand-alone CDE)
- Dianne: I am trying to figure out the difference between the caAERS elements versus the NCI standards. Examples:
 - Start date
 - Katie: One deals with the start of a course and the other is an intervention; that's the main difference, in the question.
 - Dianne: The difference is invisible to many users.
 - Present Status (required if primary AE is yes) – Present status recorded for an AE; the one we use is participant status and outcome. caAERS uses a specific AE instead of overall (similar to the start date). Again, a difference in the basic question that is not apparent to most users.
 - Lab Test [Lab category] [DSL] – caAERS is categorizing labs instead of a listing of the current tests, as is the case with the CRF standard element.
 - Unit of Measure – They are using a different unit of measure in caAERS.
 - Site of Metastatic Disease – They use a different list than the NCI Coded Values (a text term or pulling from another site).
 - Vanitha: Other disease names come from the CTEP Database; the list of values is coming from a CTEP database.
 - Katie: The sites are filling it out during the registration process (with MedDRA Codes)
- Katie: A lot of these elements are not present in Rave; they are linked to an outside system, so it is easier to change.
- Dianne: If there is something internal, and not obvious, I would be less likely to make a recommendation to change it. There will be things the typical user will not need to worry about.
 - Gwen: The majority of the differences I saw were of that nature. Meaning they are based on the structure of the CDE, mainly the question or DEC formation.
- Tina: If we were starting from scratch, where would you like to begin?
 - Dan: One thing to consider is the coded values (PV and PV meanings); it would be good to understand what we would like to see there. There are some scales that require an inherent number scale, but for others, it would be helpful to change to a short term meaning (instead of a number code). As a programmer, I have seen that changing number codes to other number codes, instead of a shortened value, can lead to more developer errors.
 - Smita: I agree, using a shortened value meaning has helped us to ensure we were not adding the wrong value; I think it is better than a numbered term.
 - Dianne: It was brought up last week by Shauna, that this would also avoid more errors and would be more intuitive for most users.
 - Smita: Identifying a list of all of the enumerated CDEs across all of the systems and prioritizing that seems like a great way to start.
 - Katie: Another benefit for prioritization, the AE forms were vetted by all of the LPOs. What we did not get into was the SAE forms, we are limited to what we can change for the value domain but I believe the question texts (the verbiage the user sees) could greatly benefit from our group looking at that content. Now may be the best time to do it (focusing on punctuation, content, and formatting).

Attendance:

Name	Affiliation
Katie Allen Ziegler	Alliance
Shauna Hillman	Alliance
Dan Jameson	COG
Smita Subramanian	COG
Wendy Wong	COG
Ginger Riley	CTSU
Mary Vienneau	ECOG-ACRIN
Tina Taylor	ECOG-ACRIN
Christina Warmington	Essex Management
Neesha Desai	Essex Management
Andrea Denicoff	NCI
Dianne Reeves	NCI
Gwen Deen	NCI
Rebecca Paulis	NRG
Vanita Patel	NRG
Vanitha Chockalingam	NRG
Angela Smith	SWOG
Cathy Rankin	SWOG
Peter Clark	Theradex