Network Rave Data Standards (NRDS) Content WG

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Agenda

- Meeting Recap

- Polling Results

- Standardization Strategy

- Next Steps

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Meeting Recap

- Reviewed the analysis from the integrations matrix
  - Discussed starting with the 45 enumerated CDEs first and determine how to code those
- Identified a list of issues with the existing CDEs
  - All caps for the value meanings
  - Ampersand
  - Use of the work "for"
  - Abbreviations
  - Value meanings are simplified versions of the actual meanings
- Discussed using shortened values rather than number codes to avoid error
- Agreed to create a style sheet to better format the forms
  - This style sheet will be used prospectively for everyday curation moving forward
- Sent out a poll to vote on which set content we will start with first: caAERS or OPEN Demography

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Polling Results

- 5 organizations voted for caAERS

- 2 organizations voted for OPEN Demography

Majority consensus to start with the caAERS data

- OPEN demography will be slotted for the 2nd Phase of the NRDS Project

NRDS Content Strategy

1. Review and prioritize the 23 caAERS forms to determine what ones we want to start with first

2. Define a set of recommendations

    1. Review the PVs

    2. Coded Values

    3. Formatting

3. Curator will provide examples with the implemented recommendations for the group to review for each form

4. Send the list of recommendations and the standardized form(s) to the NRDS Committee to review and approve.

NRDS Content Deliverables

Deliverables

1. Style guide for formatting the caAERS CRFs.
   - COG has sent existing style guides we can use as a starting point
   - The style guide will be used moving forward for curation efforts
2. Mocked up version of the 23 caAERS forms with implemented recommendations

caAERS Forms

- Adverse Event (25 Questions) – Priority 1
- Expedited Rpt Eval (7) - Priority 1
- Late AE (15) - Priority 1
- Late AE Reporting (4) - Priority 1
- Patient Status: Baseline (1) – Not include
- Patient Status: FUP (2) – Not include
- Patient Status: Trt Intervention (1) – Not include
- SAE Additional Info (16)
- SAE Attribution (6)
- SAE Con Meds (1)
- SAE Description of Events (6)
- SAE Information (17)
- SAE Lab Test & Result (10)
- SAE Participant Info (11)
- SAE Pre-Exist Condition (1)
- SAE Prior Therapy (7)

- SAE Protocol Agent Intervention (11)

Curation Style Guide

Common Issues for Question and Values

- Symbols !@#$%^&*()<>/\{}[]
- Abbreviations and Acronyms
  - Diagnoses; Anatomical Sites; Disease Status; Institutions…
- Subscript and Superscript
- Units of Measure
  - In question text
- Capitalization
- Using NCI Standards
  - When is it OK to stray from the standards?
- Use of Integers: 1 or one
- Patient/Person/Participant

Question Text (1)

- **Stand Alone Questions**
  - *If patient has been diagnosed with melanoma and is male,* has patient agreed to use contraception for the duration of the study?
- **Time Points**
  - Embedded time points in the question text
- **Multiple Conditions/Compound Questions**
  - Does patient have *A* or *B* or *C if not previously treated*?
- **Verb Tense (Past/Present/Future)**
- **Subject Verb Agreement (Singular vs Plural)**

Question Text (2)

- **Questions versus Statements - Punctuation**
  - ?
  - :

- **Capitalization**
  - Mixed
  - All Caps
  - First letter of every word

- **Use of "the"**
  - "Did patient" versus "Did the patient"

Value Domains (1)

- **Embedding Separate Questions in Value Domains**
  - Were lung nodules biopsied? Yes/No; Was tumor found in the biopsy specimen? Yes/No; Were lung nodules biopsied? No/Yes, tumor found in the biopsy specimen/Yes, tumor not found in the biopsy specimen
- **Indicator Value Domains**
  - Use established and preferred Indicator value domains
- **Complete Enumerated Value Domains**
  - Standard lists (curate entire list)
- **Missing Concepts for Permissible Values**

Value Domains

- Use of "Other Specify"
- Use of "N/A"
- Capitalization of PVs and PV Meanings
- Use of Symbols in PVs and PV Meanings
- Abbreviations and Acronyms in PVs and PV Meanings
- Duplicative information
  - PV: Upper Respiratory Tract (URT)
- Use of "/" in PVs
  - Liver/Spleen
- Length of PVs and VMs

Next Steps

- Continue developing the style sheet for the caAERS CDEs.

Reference Information / Questions

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