Network Rave Data Standards (NRDS) Content WG

Tina Taylor and Dianne Reeves
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Agenda

- Meeting Recap

- Action Items

- Review SAE Forms

- Review Implementation Process

- Next Steps

Meeting Recap

- All 4 Adverse Events forms reviewed for content

- 6 out of the 16 SAE forms reviewed for content

- Total of 67 CDEs left to review within the 10 remaining forms

Action Items

- Mix of coded values and text strings for permissible values
  - Use as is or make changes?
  - Take back to your organization and come back with a final decision by next meeting
- Cycle #
  - NCI Leadership agrees with allowing a set of STANDARD alternate question text
    - Curation team will bring back a set of alternate question text for this group to review and standardize
    - This change affects additional fields.
- AE evaluated this cycle
  - Question text is correct but CDE is wrong
  - Will need to create a new CDE and will work with Vanitha to ensure the field OID can be mapped to the field name
- Date First Learned
  - Keep Date First Learned and implement it with the date entered in Rave
  - Determine how FDA defines the date from a regulatory perspective

Implementation Process

- There will not be a formal approval process of the changes this group proposes by another committee.

- Once the changes have been proposed, the forms will be built and tested and approval will come after the testing.

- The Training/Communication WG will provide a formal approval process to use once the forms are tested.

- Next Steps for this group

  - Identify a group that will build the first 4 AE Forms

  - Identify a set of success criteria for all groups to use when testing the forms

  - Work with CTSU to understand the schedule for building the caAERS Integration Forms

Next Steps

- Continue review of the content for the SAE forms

- Continue to draft the implementation process

Reference Information / Questions

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- ## NCI Co-Lead

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