

Network Rave Data Standards (NRDS) Content WG

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Agenda

- Meeting Recap
- Review of NRDS Goals/Objectives
- Review SAE Forms
- Next Steps

Meeting Recap

- All 4 Adverse Events forms reviewed for content
- 10 out of the 16 SAE forms reviewed for content
- Total of 34 CDEs left to review within the 6 remaining forms

NRDS Project Goals

- To facilitate the implementation of selected CDEs to be used in Rave to promote science, patient safety, efficiency and the performance of meta analysis across the NCTN and ETCTN.
- Discussion Question
 - When the standardized CDEs from the caAERS Integration will be used in other forms, what attributes would people want to change?
 - Value sets
 - Question text

Next Steps

- Content Review
 - Distribute the SAE and AE before/after spreadsheet for review
 - Working group will review changes and come back with any comments/approval on behalf of their organization
- Identify a list of use cases for using the caAERS Integration CDEs on other forms
- Review style guide and provide feedback to neesha.desai@nih.gov
 - Will be posted on wiki this week and an email will be sent out
- NCI Leadership planned discussion
 - Discuss the use cases provided by this group to determine if the standardization applies only to the caAERS integration forms or anytime the CDEs are used on any forms.
 - Discuss implementation approach and timelines

Action Items

- Agree on standardized alternate question text
 - Cycle #
 - Course
 - Visit
- Reporting Period End Date
 - Remove Reporting Period from the Late AE Form and make it LPO specific question text.
 - Will work with CTSU to understand the impact of this change.
- Start date with this cycle
 - Suggestion: Change to Intervention Occurrence Begin Date
- Delay
 - Validate if the group prefers a text term or coded value (currently 1,2 Yes/No)
- Total Dose (to date) and Total dose administered (this course/cycle or reporting period)
 - These are two different CDEs. Researching to identify existing CDEs or to develop new CDEs

Reference Information / Questions

- NCTN Co-Lead
 - Tina Taylor, Health Metadata Analyst, SAIC
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- NCI Co-Lead
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