

Content Working Group

Introduction

The Content working group is made up of representatives from the NRDS committee and additional subject matter experts nominated by NRDS Committee members. It is co-led by a NCI and NCTN /ETCTN representative. The purpose of the Content working group is to identify a set of CDEs for use in Rave by the NCTN and the ETCTN. The working group will meet weekly.

CDUS Content Review

- [CDUS Content Review \(06/01/2016\)](#)

Tuesday October 27th, 2015 NRDS Content WG Meeting

The outcome of the October 27th meeting is that the set of content as reviewed and finalized by the Content WG for caAERS/OPEN is ready to send for CTSU for analysis and evaluation. CTSU will respond to all requests for changes based on their ability to accommodate the working group suggestions.

- This change will impact only the 27 caAERS forms, 1 OPEN Demography form and a small number of elements used to populate and derive the caAERS/OPEN forms.
 1. Adverse Events
 2. Expedited Reporting Evaluation
 3. Late Adverse Events
 4. Late AE Reporting
 5. SAE Additional Information
 6. SAE Attribution
 7. SAE Concomitant Medications
 8. SAE Information
 9. SAE Laboratory Tests and Results
 10. SAE Participant Information
 11. SAE Pre-Existing Conditions
 12. SAE Prior Therapy
 13. SAE Additional Information
 14. SAE Attribution
 15. SAE Concomitant Medications
 16. SAE Information
 17. SAE Laboratory Tests and Results
 18. SAE Participant Information
 19. SAE Pre-Existing Conditions
 20. SAE Prior Therapy
 21. SAE Protocol Agent Intervention
 22. SAE Protocol Device Intervention
 23. SAE Protocol Radiation Intervention
 24. SAE Protocol Surgery Intervention
 25. SAE Report Initiation
 26. SAE Reporting Period Information
 27. SAE Submission
 28. OPEN Demography

Quick Links

- [Announcements](#)
- [NRDS Committee Wiki](#)
- [Case Report Forms Wiki](#)
- [April 2017 NRDS Bulletin](#)
- [NRDS Scrum Calls](#)

Content WG Documentation

- [Content WG Meeting Materials](#)
- [Phase 1 Content Review Spreadsheet](#)
- [NRDS Standard OPEN Forms Implementation Process](#)
- [Alliance Paper CRFs](#)
 - [RAVE GL Generic Form](#)
 - [SAE Pilot Paper CRF Mock-up \(AE\)](#)
 - [SAE Pilot Paper CRF Mock-up \(SAE\)](#)

Contact Us

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NRDS caAERS Integration Content Review

Please find attached the following spreadsheets for your review and comments:

1. [Draft caAERS AE before and after recommended changes](#)
2. [Draft caAERS SAE before and after recommended changes](#)
3. [Draft NCTN/ETCTN Curation Style Guide](#)

A few things to keep in mind during the review process:

- The review period will be from **Thursday August 6th, 2015 to Thursday August 20th, 2015.**
 - If an extension is needed, please contact the NRDS Project Manager: Neesha Desai (neesha.desai@nih.gov)
 - Each spreadsheet has a column to collect comments from your group, as well as a reason for the requested changes. Please use the two columns to provide your comments.
 - Email the spreadsheets with your comments to the NRDS Project Manager: Neesha Desai (neesha.desai@nih.gov) by **Thursday August 20th, 2015.**
 - **Note remember that all comments provided must represent your organization.**
- **Note to NCTN Statistical Center Pls:** Please be sure to discuss within your Stats Center the code changes being proposed to ensure the benefits outweigh any potential challenges. One change in particular to review is changing all numeric responses of '1' or '2' to a character

response of 'Y' or 'N' (for Yes and No). There are 30 coded indicator value sets impacted by this 1,2 to Y,N coding. All of these changes can be found on both the caAERS AE and SAE CRF before/after spreadsheets.

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