

Network Rave Data Standards (NRDS) Content WG

Tina Taylor and Dianne Reeves

July 7th, 2015

Agenda

- Meeting Recap
- Goal for Today
- SAE Form Prioritization
- Formatting Review Strategy
- Review AE Forms
- Next Steps

Meeting Recap

- NCI Curators will come up with an alternate text and use it for all areas with the Course/Cycle / Alternate question text will be used. Only an approved number of alternate text questions will be approved by this content group.
- Adverse Event evaluated this cycle
 - Question text is correct but the CDE is wrong. NCI Curators identifying another CDE and working with Vanitha to apply the correct OID and text for the integration.
- Where this is a grade 0, add a description “The 0 is added for solicited CDEs as needed, and not per the CTCAE version 3 and 4.” Group agreed coded values are how they should appear.
- Date First Learned
 - Change to Date of CDMS data entry. Need to review the CDE definition. This is the starting date to determine reporting type and when it will be due (although if they are delinquent it may not be correct). Still requires further discussion with CTEP.

Goals for today

- Complete content review of the remaining 3 AE forms
- Begin content review of the SAE forms

SAE From Prioritization

- SAE Report Initiation
- SAE Information
 - SAE Pre-Existing Conditions
 - SAE Concomitant Medications
 - SAE Prior Therapy
 - SAE Laboratory Tests and Results
- SAE Description of Event
- SAE Reporting Period Information
 - SAE Protocol Agent Intervention
 - SAE Protocol Device Intervention
 - SAE Protocol Surgery Intervention
 - SAE Protocol Radiation Intervention
- SAE Participant Information
- SAE Additional Information
- SAE Attribution of Adverse Events
- SAE Submission

Formatting Review Strategy

- NCI Curator will clean up the formatting once the content has been completed and work on the style sheet.
- NCI Curator will send out the formatted content for the NRDS Content WG to review and comment outside of our regular meeting time.
 - The spreadsheet will include a before and after to show what changes have been made.
 - Will bring back all comments and review with the group at the next meeting.

caAERS Question Text	CDE Definition	PV caDSR	PV Meaning caDSR	
Attribution to study intervention	relation of the causality between the treatment modality and the specific adverse event.	Definite Possible Probable Unlikely Unrelated	DEFINITE POSSIBLE PROBABLE UNLIKELY UNRELATED	Before
Attribution to study intervention	Relation of the causality between the treatment modality and the specific adverse event.	Definite Possible Probable Unlikely Unrelated	Definite Possible Probable Unlikely Unrelated	After

Next Steps

- Continue review of the content for the AE forms
- Continue development of the style sheet for the caAERS CDEs.

Reference Information / Questions

- NCTN Co-Lead
 - Tina Taylor, Health Metadata Analyst, SAIC
 - TINA.M.TAYLOR@saic.com
- NCI Co-Lead
 - Dianne Reeves, RN, MSN Associate Director, Biomedical Standards, NCIP
 - dianne.reeves@nih.gov
- Project Management Support
 - Neesha Desai, PMP, Project Manager, NCI CBIIT
 - Neesha.Desai@nih.gov



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