Network Rave Data Standards (NRDS) Content WG

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Agenda

- Meeting Recap
- Review AE Forms
- Next Steps

Meeting Recap

- Agreed to review the content of all four AE forms first, and then to a review of the format of each item on the four forms.
- Reporting period end date or Adverse Event Final Assessment CDE
  - Eliminate this item in the integration, and both CDEs under consideration are not needed.
- Start date of first course/cycle
  - Explore the possibility of creating a set of data elements that may need different question text depending on the modality (radiation, drugs, surgery, gene therapy, etc.). This item is in the 'Parking Lot' for now.
- Adverse Event Term (CTCAE v4.0) (derived)
  - Locate a CDE that has the MedDRA 8-digit code for the Permissible value (PV) and the Adverse Event term as the Value meaning (user string). That will be used for this item.
- MedDRA AE Code
  - This item appears to have the wrong question text and the wrong CDE. Review to locate the correct CDE to be used
- Agreed that the standardized content will be the required core set of fields on each form, formatted as we agree. No changes will be made to this set of fields, but more items can be added to a form as needed.

Goals for today

- Finish content review of the Adverse Event Form
  - Discuss the course/cycle CDE and identify a resolution or action plan
- Finish content review of the Expedited Reporting Evaluation Form
- Start on the Late Adverse Event Form

Next Steps

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

Reference Information / Questions

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