Network Rave Data Standards (NRDS) Content WG

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Agenda

- Meeting Recap

- Goals for Today

- Open Action Items

- Review SAE Forms

- Next Steps

Meeting Recap

- Completed initial review of

  - AE Questions

  - SAE Information Form

  - SAE Pre-existing Conditions

  - SAE Concomitant Medication

  - SAE Prior Therapy

Goals for today

- Review the open action items for the forms that have been reviewed
- Complete review of SAE Forms

Action Items

- Course/Cycle Data
  - Use Cycle # as the question text and use the instructional text to use other values (visit, course, etc)

- Lab Type Question
  - Validate that the definition is correct

- Unit of Measure
  - Validate that the single set of values will work for all groups

- Mix of Numeric Codes and Terms
  - Determine if we want a mix of terms and numeric codes

- Reason for recommendations:
  - The goal is to create a single set of forms that can be used across groups; the ability to customize and 'swap out' question text should therefore be contained.

Next Steps

- Continue review of the content for the SAE forms

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Reference Information / Questions

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