Network Rave Data Standards (NRDS) Content WG

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Agenda

- Project Update

- Review CDUS Comments

- Discuss standardization of CDUS unique elements

- Style Guide Discussion: Quotation after Question Text

- Next Steps

Project Update

- OPEN Content
  - Received all OPEN comments from Content WG
  - Next step is to send comments for CTSU Review
- CDUS Content
  - Received all CDUS Comments from Content WG
  - Next Step is to send comments for CTSU Review
- AE Integration Content
  - Working with CTSU to plan for implementation
- SAE Integration Content
  - Moving forward with SAE integration content
  - CTSU is reviewing the content

CDEs reviewed for CDUS abbreviated and complete reporting

- **Date of last treatment**
- **Off treatment reason**
- **Off study date**
- **Off study reason**
- Participant subgroup code
- Is the participant ineligible for inclusion on this study
- Performance status (Zubrod)
- Total number of prior chemotherapy regimens
- Evaluable for response status
- Prior therapy type
- Height
- Weight
- Dose modification (Change)
- Total dose of agent for this cycle

- Units of measure for Agent
- Baseline abnormalities flag
- **Baseline abnormality using the MedDRA adverse event code (CTCAE v4.0) –**
- **Baseline abnormality grade**
- Baseline abnormality Verbatim
- Has an adverse event expedited report been submitted?
- **Response at this assessment**
- **Response observed date**
- Assessment comments
- **DLT type (using CTCAE 4)**
- **DLT (Adverse event) other, specify**

Style Guide Discussion

Punctuation - Question Text	
Item	Before
Question Text	Attribution:

NRDS OPEN Implementation

- Pilots
  - Theradex – OPEN – Backend - Rave
  - ECOG – ACRIN – OPEN - Rave

Next Steps

- Complete CDUS Final Review
- Review OPEN remaining content updates

Reference Information / Questions

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