

Network Rave Data Standards (NRDS) Content WG

Tina Taylor and Dianne Reeves

Agenda

- Project Goals
- Review Pre-registration/screening content
- Discuss standardization of CDUS unique elements
- Style Guide Discussion: Quotation after Question Text
- Next Steps

Recap

- Discussed OCI and truncation requirements
 - The OCI does not truncate PVs regardless of the number of characters.
 - The OCI truncates the data dictionary names to 32 characters because of SAS OnDemand.
 - Medidata Rave has a 50 character limitation.

Project Goals

- For content that has been reviewed and approved by the NRDS Content WG, the group has agreed to
 - **Use the same question and answer set, formatted in the same way (i.e., text) in Rave.**
 - **Question Text = Field Label in Rave**
 - **Answer Set = User Data String and Coded Value in Rave**

Standardizing CDUS Content

- Met with NCI Leadership to discuss the CDUS 25 unique elements
 - Per NCI guidance we should focus on the larger picture of standardization
 - Focus on standardizing the ones that “make sense” out of the 25 unique elements
 - Suggested CDEs to start with

- Criteria to identify which ones to standardize?

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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