Network Rave Data Standards (NRDS) Content WG

Tina Taylor and Dianne Reeves

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December 8th, 2015

Agenda

- Meeting Schedules

- CDUS Reporting Content Review Strategy

- CDUS Reporting Content Review

Holiday Schedules

- Meeting schedules

  - Tuesday December 22nd, 2015 - Cancelled

  - Tuesday December 29th, 2015 – Cancelled

  - Tuesday January 5th, 2016 – Scheduled meeting at 4:00pm EST

Recap of previous meetings

- Started reviewing the CDUS Reporting Content
  - There were concerns about reviewing
    - Items we already reviewed
    - Items the groups do no collect in Rave

- Strategy
  - Cleaned up the spreadsheet by
    - Highlighting in blue the ones we already provided recommendations for
    - Left a set of ~40 CDEs for this group to help us understand if you collect them in Rave
      - Goal: Understand requirements that drive what you collect in Rave

CDUS Forms

- Patients

- Patient Races

- Treatment Courses

- Course Agents

- Baseline Abnormalities

- Adverse Events

- Late Adverse Events

- Best Responses

- Trial Comments

- Phase 1 End Point DLTS

Next Steps

- Continue reviewing CDUS Reporting

- Update on AE/SAE Integration and timelines

Reference Information / Questions

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- NCI Co-Lead
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