

Network Rave Data Standards (NRDS) Content WG

Tina Taylor and Dianne Reeves

Agenda

- CTSU Meeting Update
- NRDS Content Review Process
- Theradex date discussion
- Review NRDS AE and SAE Integration final recommendation

CTSU Meeting Update

- NCI co-leads met with CTSU to discuss process for implementation
 - NCI submitted a draft version of the recommended changes to CTSU
 - CTSU will begin reviewing with a note that the final recommendations have not been submitted
 - NCI co-leads will submit the final recommendations after the 1 week review period by the Content WG
 - CTSU will review the recommendations and come back with feedback on what changes can and cannot be included in the implementation and reasons why
- CTSU is focusing on solutions that work across the NCTN/ETCTN
- Plan to implement the AE and SAE recommendations with the next SAE Integration phase with NRG
 - Timelines are critical to align with the next NRG implementation

CTSU Meeting Update

- Content discussion items with CTSU
 - The word “derived” is a Rave specific field and cannot be changed
 - Any changes to PVs will need to be validated that it can be accepted by E2B
 - For Form and Field OIDS CTSU recommendation
 - Recommends that Forms and Fields have OIDs that are intended to be used across groups as a standard
 - Understand that there are downstream needs such as maintaining mapping when Field and Form OIDs are changed
 - Karnofsky
 - Users will be able to choose either the code or text string

NRDS Content Review Process Next Steps

- Neesha Desai will send out the final list of recommendations for one week review by working group
 - Purpose is to review the recommendations before submitting to CTSU to review for implementation
 - Groups will provide a final vote after implementation and testing
 - There will be no extension period for this review
- Review period will be a 1 week period
 - Start Date: **September 23rd, 2015**
 - End Date: **September 30th, 2015**
- All comments should be submitted to Neesha Desai (neesha.desai@nih.gov)
- Thank you to the CTSU team

Theradex Discussion

- Discuss the onset and resolved date fields on the AE and SAE forms as they have an impact on the Central Data Repository and Web Reporting Project.

Reference Information / Questions

- NCTN Co-Lead
 - Tina Taylor, Health Metadata Analyst, SAIC
 - tina.taylor2@nih.gov
- NCI Co-Lead
 - Dianne Reeves, RN, MSN Associate Director, Biomedical Standards, NCI CBIIT
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- Project Management Support
 - Neesha Desai, PMP, Project Manager, NCI CBIIT
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