

Network Rave Data Standards (NRDS) Training and Communication WG Meeting

Holly Massett and Ginger Riley
August 26th, 2015

Agenda

- NRDS Project Update
- Voting Guidelines

NRDS LISTSERV

- NCI-NRDS-BULLETIN
 - Purpose is to provide periodic updates and announcements to all NRDS project stakeholders
- To join, send an email to NCI-NRDS-BULLETIN@list.nih.gov with the following text in the message:
 - Subscribe NCI-NRDS-BULLETIN (email address) First Name, Last Name

TRAINING AND COMMUNICATION WORKING GROUP UPDATE

Training and Communication Working Group

- Developed a voting guidelines document
 - Purpose is to describe the process of the review and voting period for each set of content
- Developed a voting form
 - Purpose is to serve as a formal document for each group to sign off on the standards
- Developing the communication workflow between the working groups and NRDS Committee
- Finalizing the August bulletin to send out to NRDS listserv
- Holly Masset will be stepping down as co-lead
 - Ginger Riley will be running the Training and Communication WG

CONTENT WORKING GROUP UPDATE

Content Working Group Update

- Following documents are in review:
 - All 4 AE Forms
 - 10 SAE Forms
 - NCI Curation Style Guide
 - Addendum
 - Includes elements that are used from other forms as part of calculations or derivations on the SAE and AE forms.
 - **We are NOT standardizing those initial forms, only the elements listed on the addendum.**

Content Working Group Update

- All comments/feedback need to be submitted by Friday August 28th, 2015
 - Received comments back from
 - Asking members to send a note before the deadline if additional time is needed
- Next Steps
 - NCI will consolidate and address comments
 - NRDS Project Manager will send out the addressed comments for final review and approval
 - NRDS Content WG will begin addressing the OPEN demography content
 - Next logical step after caAERS Integration content

NRDS Voting Process: Overview

- Provide guidelines for consistency in vote solicitation and counting.
- Ample time will be provided to organizations when preparing to collect votes.
- Meeting agendas will serve as the mechanism for alerting WG members that material presented will be voted on.
- Notices of upcoming polls will be published in the NRDS Monthly Bulletin, if time permits.

NRDS Voting Process: Stakeholders

- Stakeholders are defined as the 7 NCTN organizations responsible for implementing the standardized content in Medidata Rave
 - Alliance, COG, ECOG-ACRIN, NCIC-CTG, NRG, SWOG, Theradex
- The NCTN representative for each NCTN organization can cast a vote.
- Each organization is allowed one vote per poll.
 - The NCTN representative is responsible **to fully vet the poll questions within their organization, and provide one consolidated vote.**
 - The associated biostatistician will be cc'd on the email to be informed regarding the initiation of the formal vetting process.

Guidelines for Voting Process: Timelines for Voting

- Two week time period for each NCTN representative to fully vet the proposal within their organization.
- Feedback will be discussed at one final WG meeting
- Co-leads will determine when the voting forms are due for submission with a minimum two-week window.
 - The available responses for all votes will be Approve, Reject, or Abstain.

Guidelines for Voting Process: Timelines for Voting

- If a NCTN representative does not submit a vote by the poll end date, the vote for the organization will be considered a null
- Email requests to extend the timeline on a poll to the NRDS Project Manager
 - The NRDS project manager will work with the co-leads to evaluate the request and have the option of granting it.
 - The extension (if approved) will be extended to all NCTN organizations.

Guidelines for Voting Process: Summary of Votes

- Co-leads will review and summarize all responses.
- A proposal will be accepted when greater than 50% of Stakeholders submit approval votes.
- A tie-vote is equivalent to a Rejection, and the proposal must be revisited.
- While it is optimal to obtain a vote from all Stakeholders, it is not necessary when a response has not been received upon the due date, and an extension has not been requested.

Guidelines for Voting Process: Petition for Non-Adherence

- If an organization is not able to adopt the approved recommendations an email must be sent to the NCI NRDS Project Manager with the voting form attached
 - The details of this waiver process for these instances will be developed by the NRDS Policy WG
- The petition will be routed through the NCI NRDS Committee, and the decision will be communicated to the person(s) submitting the petition.

Guidelines for Voting Process: Voting Documentation

- A form will be used for providing the official vote and full response regarding the polled question(s).
- The voting forms must be emailed to the NCI NRDS Project Manager
 - The forms will be forwarded to the applicable co-leads responsible for consolidating the feedback and votes.
- Final status of the vote must be communicated via e-mail by the co-leads to the NCI NRDS Project Manager upon determination.