U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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

Holly Massett and Ginger Riley August 4th, 2015

Agenda

- Voting Guidelines
- Communication Workflow
- Next Steps

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 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 coleads to the NCI NRDS Project Manager upon determination.

NRDS Communication Process: Overview

• NEED

- Establish a communication workflow across NRDS stakeholders.
- GOAL
 - Ensure stakeholders are advised on key items.
- INTENT
 - Provide a workflow for communicating recommendations, decisions, key status updates to NRDS stakeholders.

NRDS Communication Process: Stakeholders

- Stakeholders: the core groups responsible for NRDS activities, recommendations and decisions.
 - NRDS Committee
 - Policy & Governance WG
 - Training & Communication WG
 - Content WG
 - Lead Biostatisticians
 - Other considerations?

NRDS Communication Process: Requirements

- Who to target
 - NRDS groups not directly engaged in the vetted recommendation/ decision/ concern?
- What type of communication
 Email/ list serv?
- When to issue a communication
 - A recommendation or decision is vetted by a NRDS WG?
 - A critical concern is identified that impacts NRDS activity?
 - WG activity is at a stand still?
 - WG activities are complete?
 - Other considerations?

NRDS Communication Process: Requirements (cont)

- What to include
 - Specify which NRDS WG owns the recommendation/ decision/ concern?
 - Specify date identified/ vetted?
 - Specify details?
 - Specify target NRDS group (if engaged)?
 - Specify impact (if available)?
 - Other considerations?

NRDS Communication Process: Proposed Workflow

- Use Case Example
 - Content WG vets a decision regarding use of Alternate Text
 - The NRDS groups need to be advised:
 - NRDS Committee
 - Policy & Governance WG
 - Training & Communication WG
 - Lead Biostatisticians
 - A communication is drafted by the PM and submitted to the coleads for review
 - Confirmed communication is issued to the NRDS groups

Reference Information / Questions

- Co-Lead
 - Holly Massett
 - massetth@mail.nih.gov
- Co-Lead
 - Ginger Riley, Senior Study Director, Westat
 - GingerRiley@westat.com
- Project Management Support
 - Neesha Desai, PMP, Project Manager, NCI CBIIT
 - <u>Neesha.Desai@nih.gov</u>