

# Network Rave Data Standards (NRDS) Committee

*Mike Montello*

[Mike.montello@mail.nih.gov](mailto:Mike.montello@mail.nih.gov)

# Agenda

- Policy/Governance WG Update
- Training/Communication WG Update
- Content WG Update
- Rave Integrations Presentation

# Policy/Governance Working Group Update

# Policy and Governance Working Group

- Recurring meeting: 1<sup>st</sup> Monday of each month at 2:00pm EST
- **\*\* This group is now meeting monthly**
- Representation from
  - Alliance, COG, ECOG-ACRIN, NRG, SWOG
- Co-leads
  - Judi Manola (ECOG-ACRIN)
  - Mike Montello

# Draft Policy Guiding Principles (from 6/15/2015)

## Minimal Necessary

- Rationale: There should be a core set of elements that we think are universally important, only standardize elements when the benefits outweigh the risks.

## Keep it simple

- Rationale: Makes sense

## Start small

- Rationale: We can test the impact of the most important changes before expanding.

## Change codes for existing data elements ONLY when a need exists

- Governance around these will be made by the Policy/Governance WG

## When creating new codes, keep it as short text strings with 10 characters or less

- Rationale: There is a high chance of error with the use of numeric codes when it comes to mapping

## When considering a new standard data element, try to use a short text string as the code where possible.

- For example: instead of “1=CR” use “CR”
- Rationale: Will prevent interference with groups’ existing coding systems

## Change data elements ONLY when necessary

- Rationale: Changes will have impact (and associated cost) on existing systems if there are changes that do not justify the associated cost

# Governance Discussion

- High level governance discussion
  - Front end:
    - 1 group creates the standardized form for all groups to use
    - Reduces the risk of error from the start
  - Backend
    - Develop an ongoing process with periodic checks

# Training and Communication Working Group Update

# Training and Communication Working Group

- Recurring meeting: 2<sup>nd</sup> and 4<sup>th</sup> Tuesday at 11:00am EST
- \*\* Potentially moving to a monthly meeting
- Representation from
  - COG, ECOG-ACRIN, NRG, SWOG, Theradex, Westat
- Co-leads
  - Ginger Riley (Westat)
  - Holly Massett



# Training/Communication Working Group Update

- Monthly Project Status Updates via newsletter
  - A listserv will be created with the key stakeholders. The email will include the following items:
    - **\*\* Question for NRDS Committee: Who else do we need to include in this listserv? Biostatisticians?**
      - Update from the NRDS Content WG
      - Update from the NRDS Training/Communication WG
      - Update from the NRDS Policy WG
      - Update from the NRDS Committee
      - Project status/milestones/upcoming timelines
      - Project changes
- The newsletter will also be posted on the NRDS Committee Wiki
- The Monthly Project Status Update will be posted on the NRDS wiki.
  - The group agreed that utilizing the wiki will provide a means of a centralized location to keep the NRDS Project Announcements.
- Currently working on the 1<sup>st</sup> draft of the newsletter and targeting to send out the 2<sup>nd</sup> week of July

# Content Working Group Update

# Content Working Group

- Recurring weekly meeting: Every Tuesday at 4:00pm EST
- Representation from
  - Alliance, COG, ECOG-ACRIN, NRG, NCIC, SWOG, Theradex
- Co-leads
  - Tina Taylor (ECOG-ACRIN)
  - Dianne Reeves

# Content Working Group Update

- Formal consensus to start with the caAERS integration content for the 1<sup>st</sup> phase of the NRDS Implementation.
  - Looking at total of 19 caAERS forms
  - Removed 3 forms because they were different across LPOs
    - Patient Status: Baseline
    - Patient Status: FUP
    - Patient Status: Tri Interventional
  - Prioritized 19 forms
    - Priority 1: 4 Adverse Event Forms

# Content Working Group Update

- Formal consensus to start with the caAERS integration content for the 1<sup>st</sup> phase of the NRDS Implementation.
  - Looking at total of 19 caAERS forms
  - Removed 4 forms because they were different across LPOs
    - Patient Status: Baseline
    - Patient Status: FUP
    - Patient Status: Tri Interventional
  - Prioritized for 19 forms
    - Priority 1: 4 Adverse Event Forms

# Content Working Group Next Steps

1. Review and prioritize the 19 caAERS forms to determine what ones we want to start with first
  - Priority 1: 4 AE forms
2. Review the content for
  - Actual variables
  - Coded values and their meanings
  - Definition's along with the use or non-use of NCI CRF standards
3. Develop a style guide for the caAERS CDEs
4. Curator will provide examples with the implemented recommendations for the group to review for each form
5. Send the list of recommendations and the standardized form(s) to the NRDS Committee to review and approve.

# caAERS Forms Review Process

1. Content WG completes all 19 caAERS Forms
  1. Content Updates
  2. Formatting
2. Deliver the CRFs to the NRDS Committee
3. NRDS has iterative reviews until the forms are approved
  1. Committee can begin doing preliminary reviews as the Content WG completes the forms but final approval will happen after all 19 forms are complete.
    1. The Content WG will provide a updates to any changes that impact the forms that the NRDS Committee is currently reviewing.



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