

Network Rave Data Standards (NRDS) Policy and Governance WG

Judi Manola and Mike Montello

Agenda

- NRDS Project Update
- NRDS Governance Discussion
- NRDS Policy Discussion
- Next Steps

NRDS Project Update

- **Briefed 2 NCI Leadership teams on NRDS progress**
 - Positive response from both leadership teams on progress of work
 - Present to Group Statisticians and Chairs - TBD
- **Completed Deliverables**
 - Provided recommendations on content and sent to CTSU for review
 - (S)AE integration content with comparison to other integrations
 - OPEN Demography
 - Agreement to use the same question and answer set, formatted in the same way (i.e., text) in Rave.
 - Develop standards for coded value but may not be monitored for compliance
 - Guiding principles for Content Working Group
 - Formal Voting Guidelines
 - Formal Voting Form
 - Communication workflows
 - News bulletins (ongoing)

NRDS Governance Discussion

- **Governance = assure compliance for use of standards**
 - Short Term Policy
 - Option 1: Review all studies prior to activation
 - Determine if we want to review a sample or all
 - Reduce the risk of rework
 - Would require time-sensitive response in order not to delay activation
 - Option 2: Review random sample of studies once or twice a year
 - Determine if we want to review a sample or all
 - Risk in causing rework for activated studies
 - Other Option? (Randomly select studies for pre-activation review?)
 - Long Term Policy
 - Automated tool to validate use of standards prior to activation?
 - 1 LPO build the forms in Rave with the standards for everyone to use?
 - Minimizes the ability for study builders to drift from the standards
 - Annual review of the standards
 - Science, regulations, and business needs will change over time.

NRDS Policy Discussion: Working Categories

- Use of data **sets** in Rave
 - All of the forms in the AE Set (naming, content)
 - All of the forms in the OPEN set
- Use of data **elements** in Rave
 - Are all elements on an approved form mandatory?
 - Can sites add additional elements to a standard form?
 - How are changes to standard elements and forms and addition of new elements and forms managed?
 - Managing changes to versions of ALS file
- Role of and process for waivers

NRDS Policy Guidelines

- **Guidelines drafted from caDSR Curation group**
- **Should there (continue to) be central curation of standard elements?** If so, by whom?
- **Policy for List CDEs such as procedures, drugs, units of measure**
 - Lists can grow over time so people should be careful about sub-setting the full list and then adding 'other'
 - Additional values should be added as needed
- **CDEs with a discrete list such as response types or status**
 - The values for lists should not be subset
- **CDEs based on external standards, such as performance or stage of disease**
 - Values can be a subset of the full set based on what a protocol will permit, however, revised CDE needs a review prior to use.
 - Avoid the use of “other” in any value set

NRDS Policy Discussion

- **Example: Question:** Type of radiation administration
- **Answer Set**
 - ~~Brachytherapy HDR~~
 - ~~Brachytherapy LDR~~
 - ~~Brachytherapy NOS~~
 - External Beam NOS
 - External Beam, 2D
 - External Beam, 3D
 - External Beam, IMRT
 - External Beam, Proton
 - Systemic radiotherapy
- **Application of Proposed Policies**
 - The standard question text cannot be changed except in approved cases
 - Example: Radiation Start Date not Intervention Start Date
 - The standard question text cannot be changed except in approved cases
 - Example: Type of Radiation administration
 - A response can be eliminated if it is not appropriate for a specific study. [Brachytherapy is not permitted based on the eligibility criteria](#)
 - The question and answer sets should follow the style guide recommendations

Next Steps

- Continue defining governance and policies

Reference Information / Questions

- NCTN Co-Lead
 - Judith Manola, M.S., Biostatistician, Department of Biostatistics and Computational Biology, Dana-Farber Cancer Institute
 - jmanola@jimmy.harvard.edu
- NCI Co-Lead
 - Mike Montello, PharmD, MBA
Associate Branch Chief for Clinical Trials Technology
 - montellom@mail.nih.gov
- Project Management Support
 - Neesha Desai, PMP, Project Manager, NCI CBIIT
 - Neesha.Desai@nih.gov



**NATIONAL
CANCER
INSTITUTE**

www.cancer.gov

www.cancer.gov/espanol