

# Network Rave Data Standards (NRDS) Committee

*Mike Montello*

# Agenda

- NRDS Working Groups
- (S)AE Update
- NRDS OPEN Demography Update
- Harmonization across systems

# NRDS Training and Communication Working Group

- **Purpose**

- Outline components of a training plan, role and responsibilities, communication workflows

- **Completed Deliverables**

- Voting Guidelines
- Voting Form
- Communication workflows
- News bulletins (ongoing)

- **Next Steps**

- Manage communications across stakeholders and working groups during implementation

# NRDS Policy and Governance Working Group

- **Purpose**

- Identify requirements to guide decisions on the adoption and usage of the standardized CDEs by NCTN and ETCTN

- **Completed Deliverables**

- Guiding principles for Content Working Group

- **Next Steps**

- Develop policies around the standards
- Define governance tiers
- Quality Assurance checks to ensure people are using the standards
- Review recommendations from the Content Working Group

# NRDS Content Working Group

- **Purpose:**

- Identify a set of standardized CDEs for use in Rave by NCTN and ETCTN.

- **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) for transmission to NCI.

- **Next steps**

- Provide recommendations on remaining OPEN forms as another aspect of integrations
- Review all elements on the OPEN forms and provide recommendations for the content the NCTN and ETCTN collect in Rave.

# SAE Integration Update

- Provided recommendations on 16 SAE Forms and 4 AE Forms
  - Final recommendations were sent to CTSU to review from an implementation perspective
  - Correction of question texts
    - Text formatting and ensuring the question is clear and easy to understand
  - Correction of definitions
    - Text formatting and ensuring the definition clearly represents the question
  - Correction of permissible values
    - Changes in indicator value domain (1/2 to Yes/No)
  - Agreement to use the same question and answer set, formatted in the same way (i.e., text) for transmission to NCI.
  
- Next Steps
  - The 4 AE forms will be included in the integration activity
    - CTSU responses for AE forms will be sent by 4<sup>th</sup> week of January

# NRDS OPEN Demography Content

- Agreed to use the 11 OPEN Demography elements in the same way
  - Same question text and answer sets
- Final recommendations were approved by CTSU
  - Correction of question texts
    - Text formatting
    - Ensuring the question is clear and easy to understand
  - Correction of definitions
    - Text formatting
    - Ensuring the definition clearly represents the question
  - Correction of permissible values
    - Changes in indicator value domain (1/2 to Yes/No)
- Next Steps
  - Downstream effects from the recommendations
    - CTRP, caDSR, LPOs, CDR

# NRDS OPEN Demography Content Change Impacts

## ■ **CTRP**

- Validate changes made are reflected in CTRP

## ■ **caDSR**

- Create new context in caDSR
- Update OPEN Demography Form
- This activity will begin the week of January 25<sup>th</sup>,2016

## ■ **LPO**

- Update mapping with internal systems
- Currently working with CTSU to outline the details of the impacts

## ■ **CDR**

- Work with Theradex to ensure changes are made to the current mapping
- NCI Content WG co-leads are meeting with CDR team to gain a better understanding of their process and plan moving forward



# Harmonization Across Systems - Outcome

- Reviewed integration CDEs across caAERS, OPEN Demography, CDUS and CTRP
  - Goal of this activity was to try to harmonize the questions and value sets across systems.
  - Majority determined it is not possible to move to numeric codes and harmonize across all the systems.
    - Groups use different codes in their internal systems; they want to retain those codes and map to the standard values.
- Intend to use the data elements that we agree upon for collection and reporting purposes
- **Final Outcome:**
  - **NCTN and ETCTN groups will use, for demography, the same questions and the same answer set.**
  - **NCTN and ETCTN groups will format and hold questions and answers in a consistent and agreed-upon format within Rave.**

# Implementation of Agreed-upon Standards

- LPOs agreed to build the forms with the new standards
- Initiate a review process to ensure the standards meet the needs of the LPOs
- CTSU will update the Rave CRF Template and post it for reuse
- Act on quality assurance procedures to manage the use of the new standards.
- Develop governance procedures
- Put training procedures in place for use of the new standards.

# Reference Information / Questions

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