# Network Rave Data Standards (NRDS) Content WG

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National Cancer Institute

U.S. DEPARTMENT
OF HEALTH AND
HUMAN SERVICES

National Institutes
of Health

# Agenda

- Meeting Recap

- Standardization Strategy

- Review AE Forms

- Next Steps

# Meeting Recap

- Based on the poll results, the group formally agreed to start with the caAERS Integration content for the 1$^{st}$ phase of the NRDS Implementation.
    - The OPEN Demography content is planned for Phase 2.
- Group prioritized the set of forms and agreed to start with the 4 AE forms first.
- Decided to remove the following caAERS forms for standardization because it is different across LPOs.
    - Patient Status: Baseline
    - Patient Status: FUP
    - Patient Status: Tri Interventional
- Discussion items for today's call
    - Using course/cycle in the question text
    - Start date of this course/cycle

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# NRDS Content Strategy

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. Question: Do we want to provide recommendations for formatting after each form or after the 1st set of AE Forms?
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.

# NRDS Content Deliverables

Deliverables

1. Style guide for formatting the caAERS CDEs.

   - COG has sent existing style guides we can use as a starting point
   - The style guide will be used moving forward for curation efforts

2. Mocked up version of the 19 caAERS forms with implemented recommendations

# caAERS Forms

- Adverse Event (25 Questions) – Priority 1
- Expedited Rpt Eval (7) - Priority 1
- Late AE (15) - Priority 1
- Late AE Reporting (4) - Priority 1
- SAE Additional Info (16)
- SAE Attribution (6)
- SAE Con Meds (1)
- SAE Description of Events (6)
- SAE Information (17)
- SAE Lab Test & Result (10)
- SAE Participant Info (11)
- SAE Pre-Exist Condition (1)
- SAE Prior Therapy (7)
- SAE Protocol Agent Intervention (11)

# Next Steps

- Continue review of the content for the AE forms
- Continue development of the style sheet for the caAERS CDEs.

# Reference Information / Questions

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