

Network Rave Data Standards

Monthly Bulletin: *July 2015*

NRDS Project Committee Overview

The Network Rave Data Standards (NRDS) Committee is being established to facilitate the implementation of selected CDEs specifically in Rave. The target audience will be the members of the National Clinical Trials Network (NCTN) and Experimental Therapy Clinical Trials Network (ETCTN). The work will be led by the NCI and NCTN.

NRDS Working Group Status Overview

Content WG

- Scope for the 1st phase of implementation is the 20 caAERS Integration Forms
 - 4 AE Forms
 - 16 SAE Forms
- Completed content review of all 20 forms
- Reviewing final content and formatting recommendations.
- Next Steps
 - Defining an implementation plan to implement and test forms in Rave.
 - Working in collaboration with the current caAERS integration activity to ensure efficient planning and implementation.
 - There will be a formal approval process of all changes to the content.

Policy and Governance WG

High level guiding principles

- Minimal Necessary
- Keep it simple
- Start small
- Change codes for existing data elements ONLY when a need exists
- Change codes for existing data elements ONLY when the benefits outweighs the risks
- When creating new codes, keep it as short text strings with 10 characters or less
- When considering a new standard data element, try to use a short text string as the code where possible.
- Change data elements ONLY when necessary

Training and Communication WG

- Developing monthly bulletin to communicate project announcements
- Identifying communication vehicles
- Creating a formal approval process for content changes
- Drafting a communication workflow across all stakeholders

NRDS Project Wiki Links

- [NRDS Committee](#)
- [NRDS Content Working Group](#)
- [NRDS Policy and Governance](#)
- [NRDS Training and Communication](#)

NRDS Project Documents

- [NRDS Project Charter](#)

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