# Network Rave Data Standards Monthly Bulletin: *August 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 group reviewed the formal voting process put together by the NRDS Training and Communication working group and provided feedback as needed.

# NRDS Working Group Status Overview

#### **Content WG**

- Completed a 3 week review period of:
  - Serious Adverse Event (SAE) caAERS
     Integration Forms
    - 4 Adverse Event (AE) Forms
    - 16 SAE Forms
    - Addendum with 8 derived elements
  - NCTN/ETCTN Style Guide
- Reviewed questions and comments with WG members
- Reviewed and provided 1<sup>st</sup> round of comments for the CTSU OPEN Demography Form
- Next Steps:
  - SAE caAERS Int. Forms & Style Guide
    - Final 1 week review period of consolidated recommendations
    - Define an implementation plan to implement and test forms in Rave
  - CTSU OPEN Demography Form

## **Policy and Governance WG**

- Next Steps
  - Identify scenarios for waivers
  - Draft policies around the caAERS integration content



## **Training and Communication WG**

- Created a formal approval process for content changes
- Drafted 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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