NRDS Content Working Group
Kick Off Meeting

Tuesday April 21, 2015

Meeting Minutes

Action Item	Who	By When
Send the proposed data sets to the working group to review including the AE elements used in the caAERS/Rave integration	Neesha Desai	4/24/15
Send an email with instructions on how the working group can submit their content to standardize and prioritize.	Neesha Desai	4/24/15
Send out meeting minutes	Neesha Desai	4/24/15

Agenda Topics

Introduction of members on the call – Neesha Desai welcomed the callers to the meeting and provided the opportunity for all members to introduce themselves.

Project Overview – Tina Taylor reviewed the current goals and deliverables for the Content Working Group. She explained how this effort is different from other Common Data Element (CDE) activities. Dianne Reeves specified that the Case Report Form (CRF) standards created should be viewed as recommendations for the first set of content to target in this group. Our goal now is implementation; as a group, we want to resolve barriers to using the CDEs we target. A proposed process was described to the group to identify and prioritize the first set of content. To start the process the working group will first agree on a set of content for the 1st phase of implementation. The curators will then perform a gap analysis based on the organizations local dictionaries. Based on the results the working group will provide a set of recommendations to standardize the data then develop a final report for implementation to take to the NRDS Committee.

Scope

- Dianne: Do we want to get to the point of creating a set of CDEs, modules, folders, etc., or simply provide the standard CDEs and note that we will not standardize beyond that?
- The group will discuss the possibility of making recommendations on identifying attributes (required, conditional, optional, etc.) for the elements. It is possible that this set of attributes will not be needed; the value of adding this notation will need to be evaluated. (Shauna Hillman question)
- Shauna: Is it already decided that we have everything in the Cancer Data Standards Registry and Repository (caDSR) versus focusing on a smaller subset? Taking a smaller set of data elements and making them standardized seems more helpful. (Meaning – do we include everything from the CRF Initiative, or start with a smaller set of content?)
    - Andrea: Prioritizing the work is a driver for the National Clinical Trial Network (NCTN), leadership really wants the efforts to be placed on standardization of the actual elements and potential forms in Rave to ensure there are core standards in Rave for data sharing and analysis across the network. I think if we focus more on the network to provide standards, it will help prioritize the work that needs to be done.

  - The group agreed that a global library would be a very helpful tool to have everything in a central place – as long as it is filled thoughtfully.

- The group agreed to submit a list of existing standards that would be helpful in identifying the first set of content. The group was asked to prioritize the list below so that the working group can agree on a set of content to start with. Shauna Hillman suggested the AE's would probably be the best first candidate. Katie Ziegler suggested to start with the OPEN CDEs as a beginning exercise for this working group. Each group will submit their information to Neesha Desai at neesha.desai@nih.gov. She will then post them on the wiki to create an inventory of standards to review and prioritize. The scope of the standards include:
  - Adverse Events
  - End of Active Treatment
  - OPEN Demography
  - Progression Status
  - Vital Status
- Our scope will be tailored (but adaptable as needed) to the following:
  - Permissible value sets
  - Formats (dates)
  - Acceptable alternate question text and meanings
  - Use of numeric or other codes
  - Clarity of definitions
  - Scientific and research-need
  - Concise value meanings
  - Naming conventional/special characters
  - Data types and field lengths
  - External Standards
- Katie: Many times the CRFs look great in an Excel spreadsheet, but once they use to build the case report form, that is when we can actually see the issues.
- Mike: This is exactly what we meant by conceptual vs. implementation-ready CDEs.

Additional Standards

- There is a need to capture and look at pertinent external standards and standards activities and initiatives (Clinical Data Interchange Standards Consortium (CDISC, which publishes CDASH data elements), Division of Cancer Prevention (DCP), etc.) to ensure we have consistent standards across the board. Include the Office of the National Coordinator and other national initiatives.
- Mike: In a global sense, we will be integrating with many systems, but our focus will be Rave/caAERS (cancer Adverse Event Reporting System)

Next Steps

- Review proposed set of content
- Begin discussion of NCTN/ETCTN (Experimental Therapeutics-Clinical Trials Network) challenges to the implementation of NCI standards
- Identify a NCTN/ETCTN co-lead for the NRDS committee
- Identify a recurring meeting time
- Submit suggestions for a first set of content to standardize in Rave to Neesha.

Attendance:

Name	Affiliation
Katie Allen Ziegler	Alliance
Shauna Hillman	Alliance
Smita Subramanian	COG
Tina Taylor*	ECOG-ACRIN
Christina Warmington	Essex Management
Neesha Desai	Essex Management
Andrea Denicoff	NCI
Dianne Reeves*	NCI
Gwen Deen	NCI
Mike Montello	NCI
Chad Winch	NCIC
Amy Krystkiewicz	NRG
Vanita Patel	NRG
Angela Smith	SWOG
Cathy Rankin	SWOG