

NRDS Communication Plan

6/8/2015

Introduction

In April of 2012 the National Clinical Trials Network (NCTN) built their first trials into Medidata Rave. Currently there are approximately 150 trials in Rave. Within that implementation a number of areas were standardized including core configuration, business rules, and integration with selected other systems and use of common data elements. Reusable Case Report Forms (CRFs) with edit checks and custom functions using local standards were developed by each NCTN Group.

The CRF harmonization activity was a conceptual effort focused on the entire NCI research community and the standards identified were by design not intended for a particular CDMS system. The emphasis was on the creating a set of content to be housed in a repository for general and public use.

The NCTN agrees in principle that harmonization of the human readable content (PVMs) and coded values (PVs) in Common Data Elements (CDEs) is important to improve efficiency and effectiveness of clinical trial data management, streamline the Rave study build process and ensure that data can be shared across the NCTN and with the National Cancer Institute (NCI). The NCTN encountered a number of limitations with the use of NCTN standards during the Rave implementation.

The Network Rave Data Standards (NRDS) Communication and Training working group is being established to support a successful transition for the NCTN/ETCTN implementation of the NCI standards by providing effective communication strategies among all the stakeholders.

Goals and Objectives

Goals

The goal of the NRDS Project is to support a successful transition for the NCTN/ETCTN implementation of NCI standards with consistent, effective, and timely communications among the stakeholder organization.

Objectives

The objectives for the NRDS Project are:

- Communicate out to the end users the “big picture” and expectations around processes and timelines
- Support implementation of the NCI standards
 - Establish trust between the NCI and NCTN/ETCTN members
 - Encourage participation and collaboration
 - Communicate changes to project stakeholders
 - Provide mechanisms for two way feedback from end-users

Stakeholders

Stakeholder
NCTN Network Groups

• Alliance
• COG
• ECOG-ACRIN
• NCIC
• NRG
• SWOG
NCTN Research Sites
• Investigators and associates
ETCTN
• Theradex
• Investigators and associates
National Cancer Institute
• DCTD
• CTEP
• DCP
• DCCPS
• CCCT
• CBIIT
• CTSU

Key Messages

Audience	Key Message
NCTN ETCTN NCI	Describe the process used in the Content WG (Iterative process), announce the proposed identified content and that is to be used in Rave by all Groups, let them know the recommendations will be taken to NRDS Committee for review and approval Announce the guiding principles identified by the Policy Group
NCTN ETCTN NCI	NRDS Committee decision on proposed content and next steps/timelines

Communication Methods

Monthly Project Status Updates via Email

The NRDS Project Stakeholders will be emailed a NRDS Project Status update on a monthly basis. A listserv will be created with the key stakeholders. The email will include the following items:

- Update from the NRDS Content WG

- Update from the NRDS Training/Communication WG
- Update from the NRDS Policy WG
- Update from the NRDS Committee
- Project status/milestones/upcoming timelines
- Project changes

Monthly Project Status Updates on the NRDS Wiki

The Monthly Project Status Update will be posted on the NRDS wiki. This wiki will be made accessible to all NRDS Project stakeholders. It provides a means of a centralized location to keep the NRDS Project Announcements.

NRDS Working Group Meetings

NRDS Content Working Group

This group will meet weekly via a virtual web session. The frequency of the meetings will decrease as the project moves forward. Each meeting will have an agenda, presentation and minutes that will be posted on the NRDS Content Working Group Wiki Page.

NRDS Policy and Governance Working Group

This group will meet bi-weekly via a virtual web session. The frequency of the meetings will decrease as the project moves forward. Each meeting will have an agenda, presentation and minutes that will be posted on the NRDS Policy and Governance Working Group Wiki Page.

NRDS Training and Communication Working Group

This group will meet bi-weekly via a virtual web session. The frequency of the meetings will decrease as the project moves forward. Each meeting will have an agenda, presentation and minutes that will be posted on the NRDS Training and Communication Working Group Wiki Page.

Newsletters

Develop a monthly or as needed new bulletin to the NCI User Community.