Network Rave Data Standards Committee Project Charter

3/25/2015

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Revision History

Version	Date (MM/DD/YYY)	Reason for Change	Author
.1	12/22/14	Original Draft	Neesha Desai
.2	1/7/15	Edits to draft	Neesha Desai
.3	1/7/15	Edits to draft	Joe Martucci
.4	1/28/15	Edits to draft	Neesha Desai
.5	3/4/15	Responded to review comments	Neesha Desai

1. Project Identification

Name	Network Rave Data Standards Committee
Chartering Organization(s):	National Cancer Institute
Charter Approval Date:	
Name of NRDS Committee Chairs:	NCI representative: Mike Montello NCTN Group Representative: TBD
Project Manager:	Neesha Desai
WG Workspace URL:	NRDS Wiki
Important Document Links:	• {Doc1} • {Doc2} • {Doc3} • {Doc4}

2. Background:

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) 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.

3. Mission, Purpose, and Deliverables

3.1 Mission & Scope:

The NRDS Committee will focus on identifying specific CDEs and facilitating their implementation in Rave. The NRDS Committee will be broken down into specific working groups to develop a set of recommendations that will support the implementation of the identified CDEs for use in Rave by NCTN and ETCTN. The working group will focus on but not limited to CDE content, training and communication, policy and governance.

The scope of this NRDS committee will be confined to pilot phase of the project which includes the 1 set of selected CDEs. Once the pilot phase has completed testing and been accepted by the NCTN/ETCTN, the NRDS committee will engage in a lessons learned session to plan for the next phase.

3.2 Objectives and Goals

To facilitate the implementation of selected CDEs to be used in Rave to promote science, patient safety, efficiency and the performance of meta analysis across the NCTN and ETCTN.

3.3 High Level Requirements

The following table presents the requirements that the NRDS implement must meet in order for the project objectives to be satisfied.

Req #	Requirement Description

3.4 Deliverables and Timeframes

Major Deliverable	Deliverable Description	Completion Date
Project Charter	Identifies the project need, cost, duration and creates acceptance to begin project	April 25th, 2015
Project Management Plan	Provides stakeholders with risk, issues and other project information related to the project	April 8th, 2015
Project Schedule	Provides the stakeholders and project team with an understanding of tasks to be completed and timeframes associated with those specified tasks	April 8th, 2015
Implementation Plan	Provides the stakeholders the critical information for developing and starting a project. It is a guide that helps program staff be proactive rather than reactive in developing their program and identifying any challenges along the way	June 15th, 2015
CDE Standardization Methodology	A business process that describes the methodology to identify and prioritize the CDEs to standardize for NCTN/ETCTN	April 27th, 2015
Set of standardized CDEs	Provides a list of selected CDEs for use in Rave for NCTN and ETCTN. These will be released quarterly.	June 3rd, 2015
User Acceptance Testing	Quality assurance that constitutes NTCTN/ETCTN acceptance of implemented CDEs	August 3rd, 2015
Training Plan	Outlines who will deliver the training, how the training will be delivered and the components of the training.	TBD
Policy Guidelines	A set of principles to guide decisions on the usage of the set of standardized CDEs.	TBD
Governance Plan	Establishes principles, responsibilities and requirements for development, maintenance and implementation of standards governance policies within NTCTN/ETCTN.	TBD
Communication Plan	Outlines the roles and responsibilities of NRDS Committee project participants in the review, approval and dissemination of information about key project processes, events, documents and milestones.	TBD
Deployment Plan	Identifies for the stakeholders and project team tasks necessary to implement selected CDEs in Rave for NCTN/ETCTN	August 14th, 2015
Lessons Learned	Identifies constraints and benefits following the complete of user acceptance testing.	August 22nd, 2015

3.5 Estimated Timeline

* This timeline is for the 1st release of content only

Task	Start	Finish
Approve Project Charter	March 25th, 2015	April 25th, 2015
Kick Off Content Working Group	April 13th, 2015	June 13th, 2015
Final 1st set of standardized content	June 3rd, 2015	June 3rd, 2015
Approve implementation plan	June 8th, 2015	June 15th, 2015
Curate content	June 8th, 2015	June 19th, 2015
Pilot	June 22nd, 2015	June 29th, 2015
Testing	June 29th, 2015	August 3rd, 2015
Acceptance	August 10th, 2015	August 14th, 2015
Lessons learned and planning for phase 2	August 17th, 2015	August 22nd 2015

3.6 Assumptions and Constraints

- The decisions made for this group are focused on the NCTN and ETCTN Rave implementation however, members of the committee should keep in mind that decisions should also be made to allow for other CDMS applications.
- The recommendations made for governance should not conflict with the governance rules for the caDSR. The recommendations should be broad enough to handle systems outside of Rave.

4. Membership

4.1 Organizational Structure

4.2 Organization Descriptions

- **NCTN Management Committee** – Made up of the NCTN Group Chairs, this committee will serve as an oversight committee for the NRDS Project. The NCTN Management Committee will receive periodic updates.
- **NRDS Committee** – Made up of 1 representative and 1 alternate representative from NCTN and ETCTN. This committee will facilitate the implementation of selected CDEs specifically in Rave. They will also report out to the NCTN Management Committee on an as needed basis and provide oversight to the various working groups.
- **Content Working Group** – Made up of members from the NRDS Committee or nominated members, this working group will identify a set of CDEs for use in Rave by NCTN and ETCTN. This group will report back to the NRDS Committee.
- **Policy Working Group** - Made up of members from the NRDS Committee or nominated members, this working group will identify requirements to guide decisions on the adoption and usage of the standardized CDEs by NCTN and ETCTN. This group will report back to the NRDS Committee.
- **Training/Communication Working Group** - Made up of members from the NRDS Committee or nominated members, this working group will outline who will deliver the training, how the training will be delivered and the components of the training. They will outline the roles and responsibilities of NRDS Committee project participants in the review, approval and dissemination of information about key project processes, events, documents and milestones. This group will report back to the NRDS Committee.
- **Governance/Compliance Working Group** - Made up of members from the NRDS Committee or nominated members, this working group will establish principles, responsibilities and requirements for development, maintenance and implementation of standards governance policies within NTCTN/ETCTN. This group will report back to the NRDS Committee.

4.3 Membership Criteria

The NRDS Committee and working groups will be open to members in the NCTN and ETCTN.

4.4 Stakeholders

Stakeholder Group	Sub Groups	Roles
Network Chairs	NCTN ETCTN	Provide oversight Members of the NCTN Management Committee
NCI	CTEP CBIIT CCCT	Provide governance Coordinate and facilitate meetings Manage project activities Communicate project status to all stakeholders Lead and facilitate the NRDS Committee Provide support to NCTN and ETCTN Stakeholders

Stakeholder Group	Sub Groups	Roles
Network Groups	NCTN ETCTN	Identify the needs of the NCTN and ETCTN Participate in the NRDS Committee and the working groups Participate in the NCTN Management Committee Provide status updates to NCI
Research staff at participating sites	Local research community	Provide input on implementation and policy

4.5 Common Roles and Responsibilities

Below is a list of common roles and responsibilities for all stakeholder representatives in the NRDS Committee.

- Discuss opportunities/issues/risks associated with NRDS and ETCTN Rave Standards implementation.
- Provide recommendations regarding proposed enhancements.
- Provide recommendations on the substance of NCI communications going to the NCI-supported clinical research community and suggest channels for dissemination.
- Provide strategic guidance to the development of standards to coordinate and implement in Rave across NCTN and ETCTN.

The NRDS Committee is made up of members representing the NCI (CTEP, CCCT, CBIIT and other NCI affiliations), NCTN and ETCTN. The committee is broken into 4 working groups that focus on a specific area of the standards implementation including but not limited to content identification, policy, training and communication, and governance. Below are the roles and responsibilities that describes the representation in the NRDS Committee and the working groups.

- Co-chairs (NCTN and NCI representation)
  - o Work with facilitator and lead to create and maintain strategic plan
  - o Work with facilitator to plan activities for group
  - o Ensure there is adequate representation in NRDS Committee and working groups
  - o NRDS Coordinating Committee provide updates to NCI
  - o Working groups provide updates to NRDS Coordinating Committee
  - o Review and provide recommendations on communication plan
  - o Provide guidance on an implementation plan for the standardized CDEs.
  - o Provide recommendation for long term CDE expansion, maintenance and compliance.
- Project Manager:
  - o Develop strategic plan for the committee and work plans for committee members
  - o Develop Plan
  - o Coordinate and facilitate meetings
  - o Create agendas and presentations
  - o Develop communication strategies
  - o Create and maintain working documents

- o Manage wiki content
- o Compile meeting minutes for each meeting
- o Ensure regulatory compliance for all documentation
- Working Group Leads
  - o Collaborate with Project Manager to
    - Develop working group project charter
    - Identify working group deliverables
    - Develop agendas and review minutes
  - o Lead the working group meeting and ensure they are working towards the project charter goals
- Members (NCTN and ETCTN representation)
  - o Provide recommendations/guidance from the viewpoint of their organization
  - o Participate in Working Group meetings
  - o Attend regularly scheduled conference calls
  - o Complete volunteer work outside of committee meetings as necessary

5. Meeting Schedule

Meeting	Meeting Occurrence
NCTN Management Committee	On an as needed basis
NRDS Committee	Monthly
Content Working Group	Weekly
Policy Working Group	Every 2 weeks
Training and Communication	Every 2 weeks
Governance/Compliance	Every 2 weeks

6. Meeting Guidelines

- Conference Calls
  - o Meeting invite should be sent out to each member in the organization chart above for each meeting
  - o The meeting invite will include the date of the meeting, time, location, web meeting links and associated event id's and teleconference information
- Agendas
  - o Agendas will be created and sent out no later than 24 hours prior to the meeting by the facilitator
  - o Agendas will be made compliant with federal regulations before posting to the website
- Meeting Minutes
  - o Meeting minutes will be taken by the Technical Administrator for each meeting
  - o Meeting Minutes will be made compliant with federal regulations before posting to the website
  - o Meeting Minutes will be sent out not later than 2 days after the meeting is held

- Attendance
  - Attendance will be recorded in a log for each meeting by the Technical Administrator
- Documentation
  - All documentation for each meeting is made compliant with federal regulations and posted on the [Network Rave Data Standards Wiki](#).
  - The list of NRDS Coordinating Committee members and working group members can be found at the [Network Rave Data Standards Wiki](#).

7. Rules of Engagement

7.1 Decision-Making Methodologies:

The Co-Chairs will be responsible for designating each position as having one of the following designations:
- Full consensus: When there is Unanimous Consensus
- Consensus: Only a small minority of the working group agrees but most disagree
- Balance of Support and Opposition: Most of the group supports a recommendation but there are a significant number of those who do not support it.
- No Consensus: No strong support for any particular position.
- Minority Consensus: Small number of members support the recommendation.

The recommended method for discovering the consensus level designation on recommendations should work as follows:
- After the group has discussed an issue long enough for all issues to have been raised, understood and discussed, the Co-Chairs make an evaluation of the designation and publish it for the group to review.
- After the group has discussed the Co-Chairs evaluation, the Co-Chairs should reevaluate and publish an updated evaluation.
- These steps should continue until the Co-Chairs make an evaluation that is accepted by the group.

Consensus calls should always involve the entire Working Group and, for this reason, should take place on the designated mailing list to ensure that all Working Group members have the opportunity to fully participate in the consensus process. It is the role of the Co-Chair to designate which level of consensus is reached and announce this designation to the Working Group. Member(s) of the Working Group should be able to challenge the designation of the Chair as part of the Working Group discussion.

8. Closure & Working Group Self-Assessment:

The WG will close upon the acceptance of the success criteria, unless assigned additional tasks or follow-up by NRDS Committee.