Network Rave Data Standards Committee
Kick Off Meeting

Wednesday March 25th, 2015

Meeting Minutes

Action Item	Who	By When
Send an email for solicitation of members for working groups	Neesha Desai	March 27th, 2015
Send out meeting minutes to NRDS Committee	Neesha Desai	March 27th, 2015
Identify a co-chair for NRDS Committee	NRDS Committee	April 3rd, 2014

Agenda Topics

Introduction of members on the call

Project Overview *(Sheila Prindiville, M.D., MPH, Director, Coordinating Center for Clinical Trials (CCCT), NCI)*

- Dr. Prindiville introduced the project and discussed the goals and proposed outcomes of the Network Rave Data Standards (NRDS) Committee activity. The NRDS project stems from the September 14th, 2014 meeting between NCI and the National Clinical Trials Network (NCTN) Statisticians where they agreed to implement select standards for common data elements (CDEs) to be used in Rave to promote science, safety, and efficiency across the network. We have put together a proposed process to initiate this activity and we are open to your feedback. We want to emphasize that this is a collaborative effort between NCI and NCTN/Experimental Therapy Clinical Trials Network (ETCTN).

Presentation *(Mike Montello, PharmD, MBA, Associate Branch Chief for Clinical Trials Technology, Cancer Therapy Evaluation Program (CTEP))*

- This is a Rave specific activity but we will be cognizant about other CDMS activities that are going on.
- The goal of this project will be to facilitate the implementation of selected standardized CDEs to be used in Rave to promote science, patient safety, and efficiency across the NCI Networks (NCTN, ETCTN & NCORP).
- The objectives of this activity include:
  - Identifying implementable CDE standards to be used in Rave
  - Providing guidance on an implementation plan for the standardized CDEs
  - Providing recommendation for long-term CDE expansion, maintenance and compliance
- This activity will be different from the caDSR/CRF Roadmap activity in that the audience will be the NCTN/ETCTN & NCORP rather than the entire research community. In addition, this project will focus specifically on RAVE and have a comprehensive implementation plan.
- Question: Are we going to talk about the form that the question is going to be placed on and how it is on the list? Standardization of the question is one level but when we look at some of the integrations, where it is placed on a form and how those forms are organized by folders could impact our ability to integrate.

    - Yes, that is something we need to tackle and standardize CRFs within selected areas.
- Question (Shauna Hillman): Is the point of this activity to reassess the CDEs that already exist or do we determine which ones we should standardize?
    - It is more the latter; the workgroups will help with that decision.
- Methodology:
    - In the current methodology we created a diagram to address the issues of our previous process and show how our new process will be different. We were originally focused on harmonization for elements used on CRFs. We started with a set of content and that content was created by compiling 400 CRFs and cutting them into individual data elements. Once we distilled it down, we had a set of content that the community reviewed. We have had a number of challenges such as the content not reflecting our needs, the human readable content was inconsistent, and code values were not always numeric.
    - In the proposed methodology we will utilize the lessons learned from the various CRF projects and pull those ideas to develop a set of improved standards. In the content group, we do plan to start talking about the type of content we should be addressing first. Once we identify what that content would be, we would want to see what this group is currently using in Rave and how you are capturing the content.

Discussion

- Angela Smith: Is there room in this project to incorporate Clinical Data Acquisition Standards Harmonization (CDASH) standards, especially the data that goes to FDA? In our experience from Cancer Research and Biostatistician (CRAB), having to translate all that data on our SWOG forms to a model that maps NCTN to FDA takes a large amount of time. It would really help to have standards that comply with those FDA requirements.
    - Dianne Reeves: I am involved with this activity and we can walk through and look at what those standards are but I agree this is a good point. Clinical Data Interchange Standards Consortium (CDISC) has 16 basic domains and if we have issues with the choice list and questions, they are willing to negotiate with us for a common ground.
    - Mike Montello: We would like to minimize administrative burden where we can and this seems like a great place, so adding those requirements to our standards will be helpful.
    - Angela Smith: Medidata has an ALS with CDASH forms on it and may be worthwhile to look into.
- Angela Smith: In the presentation, it was mentioned that there might be exceptions to some of the rules but our goal would be to minimize the number of exceptions. Will these decisions be part of the governance or decided upfront at the content committee meetings?
    - Mike Montello: Exceptions will arise during our entire process and that is perfectly fine. We are going to have cross representation but we need to ensure we have appropriate communication between our committees.
    - Shauna Hillman: It sounds like the content committee itself is going to be able to come up with the scope of magnitude of what we want to standardize. My only concern is that we need to make sure we have integration representatives on these committees.
    - Mike Montello: Yes, we do have integration representatives. We will make sure we include this into the scope

Next Steps

- NRDS Committee members to participate or co-lead the following working groups. Each NCTN/ETCTN group should send an email to Neesha Desai at neesha.desai@nih.gov with the representatives name:
  - Content
  - Policy
  - Training/Communication
  - Governance/Compliance

Attendance:

Name	Affiliation
Shauna Hillman	Alliance
Katie Allen Ziegler	Alliance
Lisa McShane	Cancer Therapy Evaluation Program (CTEP)
Mike Montello	CTEP
Andrea Denicoff	CTEP
Ginger Riley	Cancer Trials Support Unit (CTSU)
Dianne Reeves	Center for Biomedical Informatics and Information Technology (CBIIT)
Brian Campbell	Central IRB Initiative, NCI
Sheilah K Hurley	Children's Oncology Group (COG)
Steven Jong	COG
Sheila Prindiville	Coordinating Center for Clinical Trials (CCCT), NCI
Judith Manola	Eastern Cooperative Oncology Group-American College of Radiology's Imaging Network (ECOG-ACRIN)
Mary Vienneau	ECOG-ACRIN
Joe Martucci	Essex Management
Christina Warmington	Essex Management
Neesha Desai	Essex Management
Stephanie Whitley	Leidos
Walt Lee	Medidata
Anna Sadura	NCIC
Vanita Patel	NRG
Gwen Deen	SAIC
Brenda Maeske	SAIC
Angela Smith	SWOG
Cathy Rankin	SWOG
Peter Clark	Theradex
Diana Vulih	Theradex