NRDS Training and Communication Working Group Kick Off Meeting

Tuesday April 21, 2015

Meeting Minutes

Action Item	Who	By When
Draft a working document for the group to review	Ginger Riley / Holly Massett	5/12/15
Include the following components to the Communication Plan - List of Stakeholder - Roadmaps for training	Neesha Desai	5/12/15

Agenda Topics

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

Project Overview – Ginger Riley discussed the need for the Training and Communication working group and explained the currently identified goals. She provided an overview of the current high-level deliverables and specified the goal is to be as well rounded as possible to ensure success.

Work Group Goals

WG members agreed with the current goals and thought they were very comprehensive for this project.

- *QUESTION 1, Theradex (Diana V.):* What do we mean by end users, is this geared to the institutions and sites or the LPOs and study builders?
  - *RESPONSE, NCI Leadership (Mike M.):* Both but slightly more focused toward the study builders. Add on the research staff in the field, the group chairs, and the statistical staff; keep all groups in mind when sending messages.
- *QUESTION 2, NCI (Mary C.):* Is this two different things, 'Training' and 'Communication'?
  - *RESPONSE, WG Co-lead (Holly M):* Yes, this is two different areas of focuses. 'Communication' will be ongoing and required at different parts of this process; 'Training' will be more of a systematic approach, ensuring that what is developed can be used.

Deliverables

WG members agreed that the current deliverables cover the scope of the project. They agreed that the Frequently Asked Questions (FAQ) document will be critical and that an FAQ should be developed from each perspective, the site user perspective and the Lead Protocol Organization (LPO) community perspective.

- *RECOMMENDATION 1, COG (Thalia B.):* Outline the goals for the Network Rave Data Standards (NRDS) project and why it was chosen as the first wave of communication.
  - *RESPONSE, WG Co-lead (Ginger R.):* Agreed with this recommendation, it should be captured in the WG communication document.

- *COMMENT 1, SWOG (Cathy R.):* The training plan looks comprehensive but the communication plan may need additional work. There are multiple audiences and wide spread content, necessitating it to be left open for expansion as necessary.
  - *RESPONSE, NCI CBIIT (Dianne R.)*: The Clinical Trials Management System (CTMS) group within Theradex works well as a team because they strive to keep everyone in the loop. It will be important to keep this group and any potential stakeholders in the loop to ensure all are involved with the process.
  - *RESPONSE, NCI Project PM (Neesha D.):* Stakeholders can be identified and added to the plan.

Communication and Training Processes/Tools

- *COMMENT 1, Theradex (Diana V.):* An understanding of the processes is necessary. As newer institutions are coming, online training will be required, training for new users and training for users that are learning the new procedures for the National Clinical Trials Network (NCTN). FAQs will be important for this training process and even though there is a lot of documentation, a step-by-step instruction document would be useful to the site users.
- *COMMENT 2, WG Co-lead (Ginger R.):* For study management, CTSU develops a protocol specific remote data capture (RDC) training and provides site users a process document; this has made it easier for sites to train their staff internally. On the protocol level, CTSU may also have periodic training, both as a new training course or a refresher.
- *QUESTION 1, WG Co-lead (Ginger R.):* Have any others managed the EDC training or has it been more informal? Are user guides utilized?
  - *RESPONSE, Theradex (Diana V.):* This has been more informal for Theradex. We have a user guide with screen shots of our standards Case Report Forms (CRF) and routinely the statisticians have Clinical Research Associate (CRA) access to the development and user testing environment, so they can look at the forms, enter data, or look at test data.
  - *RESPONSE, NRG (Vanita P.):* At NRG, we do not have one for the Rave studies; this has been discussed internally but nothing has been formally implemented.
    RESPONSE, SWOG (Cathy R.): At SWOG, we have put together a roadmap (for therapeutic trials) that we try to stay consistent with; the roadmap contains template forms for minor adjustments depending on study or disease. The new CRA will have more training on Rave, from logging into the system to loading the data required.
  - *RECOMMENDATION, WG Co-Lead (Ginger R.):* It would be helpful for the WG members to capture their current documents, processes, and/or roadmaps for training their respective user community and bring it back to this WG for discussion.
- *QUESTION 2, NCI CBIIT (Dianne R.):* Would we entertain having one centralized approach or start centralized then decentralized for each LPO defined by criteria we do not have yet? It would be great to have one plan but it is more likely there will need to be some divergence for different LPOs.
  - *RESPONSE, WG Co-Lead (Ginger R.):* I think the latter but we can discuss as a group.

Next Steps

- The group agrees to move to the 2nd and 4th Tuesday @ 11:00 am (ET)
- Group leads will work off-line to draft an outline for the approach for the deliverables

Attendance:

Name	Affiliation
Thalia Beeles	Children's Oncology Group (COG)
Smita Subramanian	COG
Gisele Sarosy	Coordinating Center for Clinical Trials (CCCT)
Stephanie Rouillard	Eastern Cooperative Oncology Group-American College of Radiology's Imaging Network (ECOG-ACRIN)
Dianne Reeves	NCI
Holley Massett	NCI
Mary Cooper	NCI
Mike Montello	NCI
Christina Warmington	NCI, Essex Management
Neesha Desai	NCI, Essex Management
Vanita Patel	NRG
Cathy Rankin	SWOG
Diana Vulih	Theradex
Pam Rapoport	Theradex
Ginger Riley	Westat