

Network Rave Data Standards Committee Meeting

Wednesday April 22nd, 2015

Meeting Minutes

Action Item	Who	By When
Provide an update on NRDS project	Mike Montello	May 20 th , 2015
Give a presentation on the NCI integration activities	Ravi Rajaram	May 20 th , 2015

Agenda Topics

Introduction of members on the call – Neesha Desai welcomed the callers to the meeting and thanked them for all their participation in the working group so far.

Project Status (Dianne ReevesDianne Reeves, RN, MSN Associate Director, Biomedical Standards, NCIP) – Dianne Reeves gave a status update on the Policy/Governance, Training and Communication, and the Content Working Group. She covered their goals, deliverables and their next steps based on their kick-off meetings.

- All the co-leads for the three working groups stated that all working group members have been very active on the calls and they appreciate everyone putting the time and effort into make this project successful.

NRDS Committee Next Steps

Integration Activities

- Shauna suggested including Site Audit Report to the list of existing integration activities. She noted that this is very different from the congruency checker. This effort would support the Clinical Trials Monitoring Branch (CTMB) process under Gary Smith. In pharma they have a concept called monitoring, we have auditing which is similar to source verification but the resources are from a volunteer community that does the auditing process and ends up not matching the industry standard; it ends up looking different from monitoring. We need to focus on doing source document verification against data.
 - Diana: This is what Theradex does when we go on site visits for trials.
 - Shauna: There was a goal of having a report in Rave that would summarize clinical data that an auditor could audit from, but that would only summarize key data elements.
- The group agreed to add the Clinical Data Repository integration activity.
- Shauna: We want to hear from NCI on any integration plans that would impact us.

Attendance:

Name	Affiliation
Katie Allen Ziegler	Alliance
Shauna Hillman	Alliance
Ginger Riley	Cancer Trials Support Unit (CTSU)
Dianne Reeves	Center for Biomedical Informatics and Information Technology (CBIIT)
Brian Campbell	Central IRB Initiative, NCI
Smita Subramanian	Children's Oncology Group (COG)
Steven Jong	COG
Gisele Sarosy	Coordinating Center for Clinical Trials (CCCT), NCI
Judith Manola	Eastern Cooperative Oncology Group-American College of Radiology's Imaging Network (ECOG-ACRIN)
Tina Taylor	ECOG-ACRIN
Christina Warmington	Essex Management
Neesha Desai	Essex Management
Walt Lee	Medidata
Jennifer Thomas	NRG
Vanita Patel	NRG
Brenda Maeske	SAIC
Gwen Deen	SAIC
Angela Smith	SWOG
Cathy Rankin	SWOG
Diana Vulih	Theradex
Pam Rappaport	Theradex