

**NRDS Content Working Group
Tuesday January 26, 2016
Meeting Minutes**

Agenda Topics

Project Update

2 NCI Leadership Teams were briefed on the NRDS project. The NCI Leadership Teams were very happy with the current progress from the NRDS Content WG.

- Judi: Can you provide more information around the biomarkers?
 - Dianne: One area that is very high in precision medicine is the area of biomarkers. The CTRP program has a group of biomarker elements that have been used. This set is a potential set of CDEs that we can review once our immediate content is completed.
 - Joe: In CTRP, we were looking at scientific abstract information to search for common biomarkers used. It may be valuable to discuss this here so we can get additional standardization so one can look across a portfolio and identify common biomarker elements.
- Peter: Isn't there only 1 CDE for Biomarker names?
 - Dianne: Yes, but they are looking for more attributes.

NRDS OPEN Demography Implementation

- Tina provided an overview of the NRDS OPEN Demography implementation strategy.
- **Build the forms with the new standards**
 - Dianne: We are seeking one group to start this.
 - Ginger: Most of this work will likely be managed by the CTSU IT group; so the building effort from the LPO would likely be minimal (to null).
 - Shauna: Build it where?
 - Ginger: CTSU would construct it. The form would be built in the caDSR
 - Dianne: We are looking to make the versioning very clear on these forms.
 - Shauna: Are other people putting this data in Rave?
 - Ginger: If it is pushed
 - Peter: I understood that for the forms to work, they had to be in Rave (Standard OPEN forms).
 - ****Ginger:** I will follow up with Ravi or Jan about this possible requirement.

Additional OPEN Forms Strategy

- Ginger explained that we will review approximately 37 CDEs (Step information, subject enrollment, treatment assignment, and patient information for NCI Reporting forms)
 - Judi: If you have any corrections to the 4 main forms, you have to do it in OPEN.
- Peter: Can you just dump the data and not use it?
 - Shauna: I do not have a major concern, but if we cannot have data in two different places, it would be better.

Rave Integration Workflow

- Ginger presented the components of patient data workflow
 - Alliance is not pushing their checklist data into Rave as well.
 - Dianne: The difference in the way this is done, push vs. pull, is that based on the Theradex/alliance experience with some of the earlier approaches?

- Shauna: This was not available for us when we started; we have always planned to go back and change it but it has still been working well.
- Peter: There are a number of tasks we do in our IWRS (Interactive Web Response System) that is important for our internal database. We receive all the data from OPEN and push the data into the OPEN standard forms in RAVE (and push to our standard data forms). It is a way to get the same data in 2 different places.
- Shauna: Has anyone experienced delays?
 - Angela: No delay significant enough to complain about.
- Peter: Is it either 5 or 6? We only do 6, is there anyone who does both data flow 5 and 6? One is coming from OPEN and one is coming from the group.
 - Angela: We are getting the checklist from OPEN
 - Ginger: This workflow may have been updated
 - Alliance and Theradex uses step 6 as the way data is getting into RAVE from OPEN.
- Dianne: It would help if we can show where this particular flow pertains to (i.e. show how which group handles each workflow).
- Ginger: Do we do the push for ECOG/ACRIN?
 - Judi: Yes
 - Wendy: I will have to check
 - Vanita: I will check

Additional OPEN Forms Review (CDISC Reporting)

Subject Enrollment Form

- CDE ID 3314240 – Enrolling Site CTEP
 - No comments
- CDE ID 2192796 – Lead Organization
 - Dianne: The definition needs to be redefined to explain what a center needs to be a lead institution.
 - Judi: If it is a lead organization, I do not know why they need to define that at the enrollment. Is it for accrual?
 - Joe: We use the definition as the organization for the overall
 - Alliance indicates it as the LPO
 - Dianne: It is pre-populated
 - Ginger: For NCTN trials, the LPO leads the clinical trial
 - Peter: I can confirm, when we looked up one of our NCTN trials, it does not show Theradex, it has the institution where the PI is running the study.
- CDE ID 2746541 – Enrollment Date (automatically pulled from the date the form is being phased in OPEN)
 - Dianne: Is enrollment date tied to the signed inform consent date?
 - Judi: No, they can sign the consent form on a different date.
 - Dianne: If it is a system generated field, we should note the definition.
 - Shauna: In our system, it is the date the registration occurred.
- CDE ID 1925 – Participant Subgroup Code (NCI Standard)
 - Judi: Protocol submission worksheet
- CDE ID 2453595 – Is the Patient currently receiving treatment on a study? (non NCI Standard)
 - Dianne: We need to change to text instead of number for PV/VM
- CDE ID 2003315 – Performance Status (Zubrod) (NCI Standard)

- Dianne: This one needs to remain a numeric PV
- Dianne: Zubrod is a really old standard, I wonder if NCI would want to update to ECOG?
- Judi: What is the source of this information?
 - Tina: Some of these forms are populated from other forms in the system and vary from one group to another.
 - ****Dianne:** We can follow-up on this item for the next meeting

Next Steps

- Next meeting is scheduled for Feb 2 @ 4:00 pm (ET)

Attendance:

Name	Affiliation
Angela Smith	SWOG
Cathy Rankin	SWOG
Christina Warmington	Essex Management
Dianne Reeves	NCI
Gwen Deen	SAIC
Ginger Riley	CTSU
Joe Martucci	Essex Management
Judi Manola	ECOG
Neesha Desai	Essex Management
Peter Clark	Theradex
Rebecca Paulus	NRG
Shauna Hillman	Alliance
Leon Kalbfleisch	COG
Tina Taylor	SAIC
Vanita Patel	NRG
Wendy Wong	COG