

**NRDS Content Working Group
Tuesday February 2, 2016
Meeting Minutes**

Agenda Topics

NRDS Recap – Neesha Desai provided a recap of the previous meeting(s) and reviewed the current open action items

- Previous Action Items
 - Determine if the OPEN Standard forms are required in Rave
 - Ginger: We should have an answer for this by the end of the week.
 - Verify source for NCI Reporting Forms
 - Neesha: This is a placeholder for the data such as for SAE Integration. As the scope has changed for this integration, this form will be on hold until CTSU has an opportunity to review and provide further guidance on the source of this form.
 - Peter: Theradex has assumed that form would be present as one of the standard forms. The CDR project is utilizing a few elements on that form; we may need it to be a standard, even if it is not required for the SAE Integration.
 - Peter to confirm internally and CC Ginger on the email to CTEP
 - Theradex volunteered to be the pilot organization for the OPEN Demography implementation.
 - Groups to verify how their data gets into Rave
 - Alliance – Pushes directly into Rave
 - Theradex – Pushes directly into Rave. In every instance until now, we have pushed the data from our IWRS into Rave. OPEN sends the data to IWRS and we send to Rave ourselves. We have a current study we need to get started and they do not want to follow our normal directives for patient ID format. In order for them to use their format, they will not be able to use our IWRS system, so we will likely do a full push to Rave; there is flexibility to use either method.
 - NRG – Pushes their data into Rave
 - COG – Pushes their data into Rave
 - SWOG – CTSU pushes from OPEN to Rave
 - ECOG-ACRIN – CTSU pushes from OPEN to Rave (to confirm)
 - NCIC – Unverified

Additional OPEN Forms Review

STEP Information

- CDE ID – 2002093
 - Rebecca – We have multiple step registration where steps are sent to outside areas then step 2 we randomize it. Not sure if treatment intervention is applicable.
 - Shauna – Also have a step registration 0 for pre-registration
 - ECOG – Proposed Study intervention or protocol intervention or protocol activity
 - Rebecca: I don't think intervention is applicable because there may not be an intervention
 - Andrea: Many times I have seen groups use Step 0 and call it screening because NRG also had studies that we call it screened for intervention to see if their tissue has the appropriate pathology mutation for the study.

- Andrea: We can call it protocol step and define protocol step is the first patient activity of the study
- Alliance: Our pre-registration is also the same as screening, pre-registration is an open term and applied to many scenarios, such as samples being sent, patients getting pre-registered in the study,
- Group agreed to use Protocol Step
 - Alphanumeric designation used to describe a component of a protocols activity that requires a separate registration. Some trials may have 1 step some may have multiple steps.
- CDE ID – 330310 – Event Description
 - Judi: Should we call it Step Description
 - Dianne – It is probably generic so you can use it on other settings
 - Peter: Is there always a correlation between the step value and the description
 - Dianne: You could couple multiple things together, it typically does not stand on its own
 - Peter: If you have multiple steps you have multiple entries in the log.
- CDE ID – 3302859: Tracking Number –
 - Dianne: This is generic, do we need it to be more specific to define a specific step tracking number. It is an identifier
 - Judi: What is this tracking number? Is it created in OPEN or Rave?
 - Shauna: The tracking number is created in OPEN not in Rave.
- CDE ID – 2740240 Treating Investigator
 - Vanita: This is a drop down with last name, first name and they just select a physician
- CDE ID: 2172 – Site Register – No Update
- CDE ID: 2152 – Crediting Group – No Update
 - Shauna – We need to add the LPO Name and Credit for Enrollment in the definition.
- CDE ID – 200224 – Crediting Physician
 - Vanita: It's the treating physician that is copying over from treating investigator
 - Shauna: Treating physician is the one treating the patient; the crediting one may be the group you are giving credit to.
 - Kristina: I don't have a specific case that they are different but it could happen.
 - Andrea: I have seen it when the patient has been transferred from one facility to another
 - Wendy: Treating physician name and investigator name is different in a drop down list
- CDE ID – 2001626 – Arm Name – No Update
- CDE ID: 3370375 – Event Date
 - Dianne: We need to simplify the definition
 - Judi: We need to add the registration date for the step in question
- CDE ID: 3412598 – Event Time – No Update
- Treatment Assignment Code – No Update
 - Judi: There is a document on how to set these up, we should be cross reference that document.
- Treatment Assignment Description – No Update
- Current Site CTEP:
 - Dianne: What does current mean?
 - Shauna: If someone is transferred, they could have a different site.
 - Peter: The current site could be the enrollment site but the definition is limiting.
 - Dianne: Current site is the treatment site

- Peter: Sometimes their enrollment is transferred
- Gwen: The enrollment never changes but they can be transferred back and forth between sites and is associated with a date
- Judi: Need to add the word site in the definition
- Peter: Need a CDE to not reference the act of registration
- Shauna: We should look into the OPEN forms to see the instructions
- **Ginger to review the instructions for the forms**
- Enrollment Time
 - Shauna: Time stamp when OPEN saves the registration step
 - Andrea: The group will let OPEN know which to link to accrual sets when there are multiple steps
 - Dianne: Enrollment date is linked to the formal accrual of the study

Next Steps

- Next meeting is scheduled for Feb 9 @ 4:00 pm (ET)
- **Ginger to find an OPEN resource to join the call**

Attendance:

| Name | Affiliation |
|----------------------|------------------|
| Shauna Hillman | Alliance |
| Kristina Laumann | Alliance |
| Wendy Wong | COG |
| Leon Kalbefeisch | COG |
| Ginger Riley | CTSU |
| Judi Manola | ECOG |
| Christina Warmington | Essex Management |
| Neesha Desai | Essex Management |
| Andrea Denicoff | NCI |
| Dianne Reeves | NCI |
| Rebecca Paulus | NRG |
| Vanita Patel | NRG |
| Gwen Deen | SAIC |
| Tina Taylor | SAIC |
| Peter Clark | Theradex |