

**NRDS Content Working Group  
Tuesday February 9, 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
  - Peter is going to confirm internally then send an email to CTEP regarding making the NCI Reporting Form a mandatory part of CDUS full reporting.
    - Peter: Not completed.
  - ECOG-ACRIN to confirm that CTSU pushes their content from OPEN to Rave
    - Judi: confirmed
  - Ginger to find an OPEN resource to join the NRDS Content call moving forward
    - Ginger introduced Lucille Patrichuk and Kasi Perumal

## **Question/Answer Session** – Tina Taylor

- Is there a source that provides clarity for the questions and definitions on the forms we are reviewing
  - Judi: One resource is the CTEP resource and guides for the system; I can send that around
- Identify the origin of the data elements from each of the groups
  - Lucille: What fields are we discussing? Here it sounds like the 4/5 standard forms from OPEN. The data is pushed from OPEN to those forms. For the Alliance, they populate the data from their own database.
  - Peter: Theradex also has the data come from our database
- Questions from Gwen:
  - Does enrolling come from the CTEP database?
    - The CTEP ID for the enrolling institution is set up in the CTEP database and then sent to RSS. From RSS, we have all of the sites. We have all of the rosters there, so when the user logs into OPEN, all of the sites show up for the user and they have to select which site they are affiliated for, based on the trial.
  - Current CTEP Site, how is that different from the enrollment site?
    - This is for patient transfer (or possibly a merge). OPEN currently has a transfer and update module, so the site can transfer the patient as needed. OPEN cannot push the patient transfer, it is a manual process.
  - Enrollment date is when the Phase is valid?
    - This is when they are ready for the step. Each step is treated individually, so they need to complete the enrollment for each new step. Then they will need to enroll in the subsequent step if needed.
    - There is an initial enrollment and a step enrollment
  - Group Data, the lead org is the LPO, what is this line pertaining to?
    - This is a placeholder, just in case the LPOs want to add something. Right now it is usually defaulted to N/A.
  - Source Application
    - That would be OPEN on which application pushed data – OPEN if OPEN or LPO depending on who pushes it.

- Tracking Number, what sort of ID number is that?
  - That is a tracking number OPEN creates for tracking (generated by OPEN)
- Treatment investigator, is this the physician administering treatment?
  - Yes
- Crediting Group, is this the LPO or the individuation clinic, hospital, or site?
  - It is the network group that is being credited for the enrollment (payments and responsible for audit activities). The hospital is choosing which group they are crediting with the enrollment. It applies to the NCTN Network Group
- Treatment assignment code – This is more technical; if you change the prescribed dose on an arm, it will change the treatment assignment code.
  - Peter: These are defined in the CTEP
  - Dianne: Will we make the definition that specific or will we leave it broader? The more specific we make it; the harder it is for the whole community to use.
  - Judi: This code is very technical in nature, the way it gets used in the systems; it gets handed off from registration. There is a lot of going back and forth between the groups and the PIO; errors in this code can cause errors with SAE reporting. I think it would be best to keep this one specific.
  - Dianne: In the name, we need to specify it is a CTEP Treatment Assignment Code
  - Judi: Is this field used if the trial is not from CTEP?
  - Shauna: We would just not use it if it was not from CTEP
- Patient ID – is the patient ID by LPOs or OPEN?
  - LPO's patient ID, depends on who is leading the trial. CTSU can also do patient enrollment

## OPEN Forms Review

### *Subject Enrollment Form*

- CDE ID 3212399 – Group Data, this is a placeholder, what do the centers see?
  - Alliance – Research to see which we see
    - Shauna: I do not see this in this form
    - Kristina: We are populating it with a version of the site name, but it is likely being pushed from our study, but not from OPEN.
  - COG – N/A, AA, and some or Null (some studies are different)
  - ECOG/ACRIN – N/A
  - NRG – N/A
  - SWOG – N/A
  - SWOG – No opinion either is fine.
  - Theradex – N/A
- CDE ID 3302840 – Source Application, what do the centers see?
  - Alliance – Ours is from OPEN, even though they push the data
  - COG – Open or AA CC CD FF
  - ECOG/ACRIN – Open
  - NRG – Open
  - SWOG – Open
  - Theradex – We have Open, even though it is coming through IWRS
- CDE ID 3370377 – Date of Intervention/Treatment Assignment
  - Dianne: Lead with the treatment part, not the assignment but this can be cut down considerably.

### Open Forum

- Judi: We may want to review the protocol admission sheet when the full protocol is submitted to PIO, some of the questions we have may be in there.

### Next Steps

- Next meeting is scheduled for Feb 16 @ 4:00 pm (ET)

### Attendance:

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