

**NRDS Content Working Group
Tuesday October 13, 2015
Meeting Minutes**

Agenda Topics - DRAFT

Project Status Update – Neesha Desai provided an overall update to the group.

NRDS Content Open Action Items – Neesha reviewed the current Open Action Items with the group.

- SAE Integration – Onset Date and Resolution Date
 - Conditionality Rule: Only complete if reporting to CDUS complete.
 - Shauna: Can you clarify what it means when it says the resolution date is important but not required.
 - Dianne: Per Mike Montello, the onset date and resolution date will be required in the future for CDUS complete. We can take this back to CTEP and determine how they would like to implement the change.
 - Shauna: Both of these dates will add burden to the sites; if it is added, I hope there is good scientific merit for it.
 - Andrea: This may be data that is not used.
 - Gwen: Currently Onset Date is mandatory for CDUS complete but Resolution Date is not.
- SAE Integration – PV for Indicator Value Domain
 - Dianne: We discussed this with the NCI Leadership group and they recommended each representative take this back to their organization for another review. There are a lot of impacts to make this change and we need to make sure everyone understands that.
 - Shauna: Is this asking if we want to use Codes for CDUS variable?
 - Dianne: We are asking if it makes sense to make these indicators Yes/No or can we keep it as 1/2.
 - Peter: Are we just talking about Yes/No or all codes in CDUS?
 - Dianne: Here we are speaking about one thing but it does bleed over into CDUS. Leadership felt they heard the value for having numeric codes for a number of reasons. If there is a good reason to change to Yes/No indicators for this particular case?
 - Shauna: For the Yes/No, we might agree, but for other areas, we may not agree.
 - Dianne: Is CDUS coding all numeric?
 - Gwen: Yes
 - Peter: Is there a way you can quickly show us the value domain for the coding for the CDEs?
 - Gwen shared the abbreviated value domains: Trial status (coded but not numeric), Yes/No (numeric), Female Gender (numeric), Ethnicity (coded numeric), Method of payment (coded numeric), Race (coded numeric)
 - Shauna: I like your idea to let us think about this for another week. I still think there is an importance for using codes when it makes sense.
 - Peter: Those set of CDEs that are connected to CDUS items; it makes sense to have a consistent plan amongst those. To follow the indicator that Yes/No should be coded but the others are numeric, it seems unbalanced.

- Dianne: Would it be helpful if we provide this part of the spreadsheet sent out to discuss with your group?
 - **Action Item** – Gwen: I will provide the list of CDUS Enumerated Values
 - Peter: If we can just see the CDEs that are relevant, it would be helpful to see the recommendations as well.
- Judi: The mapping that Theradex is working on will eventually replace CDUS reporting, but that will be years down the road?
 - Peter: We do not know the timeline, but it will be at least a year before this replaces CDUS abbreviated. I believe the data will still be going to the old style database but it will be going via an automated process.
 - **Action Item** – Ginger: I will review that process; as soon as I find out; I will send an email to the group.
- OPEN Demography – Disease Coding
 - Judi: We are currently using the NCI CTEP disease code (subset of MedDRA codes)
 - Dianne: We will be looking at how using the names will fit with ICD or SNOMED going into the future. We want to find something that has the specific terms within them that is a more acceptable terminology across healthcare. For now there will be no change.
 - Judi: Is the same thing true for toxicity codes?
 - Dianne: No, MedDRA is still a good fit for that. Version 5 will be coming out.
 - Cathy: There are a few additional codes and some clarifications on grading, based on the draft sent out over the summer.
- OPEN Demography – SSN#, Full Name, Patient Initials, Patient Hospital #
 - Dianne: Much of the time SSN may not be used but there could also be an issue with patient identification.
 - Andrea: Some sites have been told by their institution that they are not allowed to provide the SSN.
- OPEN Demography – Country Code
 - Ginger: We have plans to remove “Other”. We are waiting on some specific information from other organizations. There is one group (NRG) that currently uses “Other” but they are looking to change.
- OPEN Demography – Zip Code
 - Andrea: DCP and NCI are looking to use zip code as a proxy for deciding health disparities; if they can get the full 9 digit code, they can get more detailed information. Patient zip code is currently a requirement in CDUS.
 - Shauna: Are we going through this list to decide if there are scientific needs or make these items mandatory?
 - Dianne: We are sharing the feedback from the NCI Leadership group.
 - Andrea: I do not know all of the fields that are mandatory or not mandatory; is this not mandatory?
 - Dianne: In OPEN, it is not a mandatory field.
 - Peter: If it is required for CDUS, it is mandatory, but perhaps not mandatory upon patient registration.
 - Rebecca: Mandatory for NRG of Patients within the US
 - Judi: Mandatory for ECOG-ACRIN of Patients within the US
 - Angela: Mandatory for SWOG of Patients within the US
 - The thought was that CTRP did not include it.
 - Joe: We have the field available for CTRP; mandatory if country is US. It is technically conditional because it is based on whether or not the patient is in US.

- What would go in for a patient that is being registered from outside of the United States?
 - Dianne: The question text is US only.
- Shauna: I do not think that adding zip code does not add burden for the site but adding the resolution date may add a burden for the site.

Open Forum

- Judi: In RAVE, there is a banner to double check and ensure you have the right patient, does anyone else have this?
 - Peter: We do not
 - NRG has a strip across the top to provide the patient number
 - Angela: This is study specific and configurable.
 - Judi: This is a very helpful banner.
 - Shauna: This might be good when we discuss standardizing the user experience.

Next Steps

- Final vote regarding changing PVs for indicator response from text to numeric due 10/20/15. We will take a final vote on the call.
- Kick off the NRDS OPEN Content Final Review – The spreadsheet with the final recommendations for the OPEN content.
 - Ginger: The goal is to get most of these recommendations across; most likely, if we cannot, it is more from a technical system endpoint.

Attendance:

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