

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

## **Agenda Topics**

**Project Recap** – Neesha Desai announced a clarification from the last meeting that the OCI does not truncate PVs regardless of the number of characters.

**Project Goals** – Neesha Desai reviewed the project goals of the group. The group agrees to use the same question and answer set, formatted in the same way in Rave.

**CDUS OPEN Content Review** – Gwen Deen reviewed the CDUS OPEN content to identify potential opportunities of standardization.

- Wendy Wong: Should we use coded values across rather than having PVs of the valid values for CDUS? I am concerned about the consistency of the PVs across using CDUS data elements.
- Dianne: In general we do want to be consistent. There has been discussion on when to use text strings vs codes; we have decided that for reasons of making sure that what we have these data elements will match up with whatever groups are using in their local system, we wish to avoid codes. There is a caveat that when those codes have real meaning. Some of these things have meaning embedded in the codes. If there is ever a chance there could be errors we will default to use short text string.
- Peter Clark: As a computer scientist I support the use of codes, but that is not purely from a computer storage point of view. I have had to stand back and go with the group decision on what is more interested on what the data looks like from a human perspective.
- Dianne: We also talked about once we finish all this work and take a look at the PVs and see if we can shorten them up at all. We want to avoid things that are really long.

**Pre-Registration/Screening Discussion** – Andrea Denicoff led a discussion to identify ways to standardize the steps and the step descriptions for screening and pre-registration.

- Andrea: Based on some reports, there are many variations in how the steps are described. Given that more and more of our trials have patients tumors being framed for genomics, and the use of the term pre-registration vs a term that is more appropriate for a patient who has signed a consent form that has registered for the screening part of the study. Andrea showed current studies and how people used it. With seeing the variation across the network, would there be interest in harmonizing a set of this content...step 0 and step 1 at least?
- Angela: There is room for consistency within our group, I think that we have evidence of step 0s but in general we avoid them and treat a step 1 as a screening step. Another thing that factors into our decision on the label is how to distinguished it in step in vs a multistep study. I like the idea of getting a little more consistency but not sure how we can say step 0 will always be called this.
- Andrea: Sounds like you have a type of SOP for classic standard study then one that has many more things.
- Wendy: COG is going to have a step study 0 coming.
- ECOG/ACRIN: Melinda: I think it would be great to standardize these things but there are times when we might need to step outside, agree that we could do a better job at being consistent.

- Angela: Other than the obvious making it consistent goal, what else is gained by improving this? From users or integration or technical aspect.
- Andrea: It would help the users, some of it would line up with the backend of OPEN. When the group sends the information to CTSU, it's not so obvious where the accrual flag should go. It would improve that process as well. Within the site making different protocols from ECOG and NRG, the terminology is different.
- Angela: I would be willing to participate in a discussion on consistent definitions, I think there would need to have flexibility to apply those to steps. If we have consistent definitions, it would be easier.
- Andrea: I do see more complicated trial design. Create a style guide for nomenclature.
- Rebecca: I agree that standardization would be a benefit, but feel like it is outside for the scope of this group. It's more the people who draft the document.
- Ginger: One of the expectations that we have for any items in this group is the review and the vetting process that the items are taken back to the internal organizations. Would that satisfy for the comments from NRG?
- Rebecca: Yes it could be done, this is not within the scope of the content of NRDS.
- Andrea: If someone could articulate, in terms of this content what is the role of this group?
- Dianne: We are charged at looking at the standards, come up with a final set of content that we all agree upon that could be expected to be used in Rave to collect data.
- Angela: What do you think of the standards end user group take this on? Core configuration group? The standard end user experience working group, their responsibility is to look at things globally in Rave and identify areas where we could be more consistent.
- Ginger: That group's focus is so Rave bound, and we are tying into OPEN.
- Lucile: Do the standard enrollment forms in Rave have these generic name for each OPEN form?
- Angela: The label in OPEN does show up in Rave.
- Andrea: 1 or 2 people say they might be interested on a more common set. ECOG ACRIN
- Angela – The best place to start is the definitions of what these things mean. The label and steps is secondary.
- The group agreed to kick off another working group outside of this project to standardize the definitions for the steps.

## CDUS Reporting

- Dianne: The groups are collecting many more granular reasons for things like off treatment or off study then are present in the standard data elements, does that mean that is an element that we should not standardize and use the mapping tool, or is that an item we should particular standardize? Does that make it something you want to standardize?
- The group agreed the dates and numeric values can be standardized
- The group agreed that free text fields can include a criteria to not exceed a certain amount of characters.
- Off Treatment Reason
  - COG: Has over 100 values depending on the protocols
  - SWOG: 10 values
  - ACRIN: Different values for imaging
  - NRG: 9 values – using the standard NCI PV for off treatment

- Theradex: 23 reasons but that includes off study, we have a mixture of off treatment and off study
- Off Study:
  - Alliance: We don't capture this data on a CRF, we derive it when we report it to CDUS
  - SWOG: Does not capture either, just derive
  - NRG: Does not capture
  - Theradex: has it on their CRF
  - ECOG: Does not capture
  - COG: Captures off study reason on each reporting period, 5 reasons
- Participant eligible for inclusion on the study
  - Everyone agreed to standardize it to yes/no
- Performance status for Zubrod
  - Group agreed to standardize Zubrod – sticking with the codes
- Response evaluation status:
  - Angela: Derive
  - ECOG: Derive
  - NRG: Derive
  - Alliance: Derive
- Baseline Abnormality Flag
  - Angela: Asks it directly
  - Alliance: Derive based on abnormality in detail
  - ECOG - Derive based on abnormality in detail
  - COG: Asks it directly
  - NRG: Derives
- List of Prior Therapy – Candidate for standardization
- If I am asking all these questions on my CRF and getting an answer, does it matter if I ask additional questions along with prior therapy?
  - No as long as you use this set
  - SWOG: Map to these choices, varies from study to study
  - Alliance: Don't capture this data in this format; if it's needed for the study we are collecting the details.
  - ECOG: Specific form we do for CDUS Complete studies, we might be collecting additional prior therapy in a log line form, additional ones may be on a separate form.
  - Theradex: 17 different prior therapies, it is a check all that apply and I would say we are asking those particular questions...there is a few we are not asking about.

## Next Steps

- Next meeting is scheduled for May 3<sup>rd</sup>, 2016

**Attendance:**

<b>Name</b>	<b>Affiliation</b>
Kristina Laumann	Alliance
Phoebe Chang	COG
Wendy Wong	COG
Justin Davis	COG
Ginger Riley	CTSU
Lucile Patrichuk	CTSU
Melinda Flood	ECOG-ACRIN
Miriam Bischoff	ECOG-ACRIN
Christina Warmington	Essex Management
Neesha Desai	Essex Management
Dianne Reeves	NCI
Vanita Patel	NRG
Rebecca Paulus	NRG
Gwen Deen	SAIC
Tina Taylor	SAIC
Angela Smith	SWOG
Cathy Rankin	SWOG
Peter Clark	Theradex