

**NRDS Content Working Group
Tuesday December 1, 2015
Meeting Minutes**

Agenda Topics

Meeting Recap/Holiday Schedules

- The members in this group agreed to use the content “as-is” and that the next priority is CDUS reporting. Many members of the working group will not be available for the Dec 22nd and Dec 29th meeting.

Update on AE/SAE Integration

- We have not heard back from CTSU regarding our final recommendations for OPEN and SAE but we are working with them about a timeline for the integrations; we are hoping we to have CTSU comments by the end of the week.
- Peter Clark sent out a Persistent Adverse Event Reporting for CDUS Complete Studies for additional options of persistent AE reporting.

Discussion

- Cathy: Are the start and stop dates reported for all CDISC reporting? That information would need to come from CTEP to our group statisticians.
 - Peter: Currently CDUS reporting does not require the onset and report date but since we are working on forms for the future, this is covered.
 - Cathy: The decision on the increased detail should come from CTEP to our leadership. There is some concerns from SWOG on this level of detail.
 - Peter: Mike has said that CTEP was mandating the use of these fields and it will be announced on a future call. We are working on standard forms and this should be discussed, even though it has not been officially announced. The decision can be made not to include this now and then changed in a few months is needed.
 - Cathy: These standards implement a lot more training, cleaning, and possible errors for the sites and LPOs.
- Shauna: I agree with Cathy. Did I hear you say you are assuming the AE is ongoing until it is stopped?
 - Peter: My preference is that it be an explicit data entry action to say that it is ongoing but some of my team found an industry standard that the ongoing flag be atomically set when the record is created. The assumption is that the AE continues until someone enters a resolved date; at that time the ongoing checkbox is turned off.
- Rebecca: Do you know if there will be limitations based on grades; will it be required for Grades 1 and 2?
 - Peter: I do not know, but I can investigate. I know for NCTN studies it is required for all grades but I am not sure about others.
 - Rebecca: Within NRG, some of our studies are a maintenance drug and progresses until the patient says something.
- Andrea: Did you mention to Mike that you were going to discuss this on the agenda today? It seems that there are many questions that you cannot answer at this point. I imagine the questions raised are hopefully already being discussed. I am not sure if it is very helpful to bring it up at this point.

- Peter: I did not specify it would be on the agenda today but I did not to him that I was going to introduce the idea of the ongoing flag. Mike did note that the official announcement will be forthcoming.
- This discussion was tabled at the meeting and determined there would be another time outside of the NRDS Content WG to discuss it.

Review CDUS Reporting Content

- Are all variables collected for full CDUS reporting?
 - Neesha: Yes.
- Shauna: What is the After Text?
 - Brenda: The CDUS After Text is for after the decisions have been made and per the already approved standards.
- No comments on the first 2 elements Collections 2746459 and 1832
- Collections 1833
 - Shauna: Date Report submitted to CDUS – is that something we will collect in Rave?
 - Rebecca: Most of this stuff, in the collection section will not be collected in Rave.
 - Brenda: These are derived.
 - Shauna: I want to make sure we do not have to create additional elements to have these collected to Rave.
 - Rebecca: Most of this is not patient data and I do not see a reason for this group to look at these.
 - Tina: Agreed, maybe we should review another form first.

Next Steps

- Priority 1 – CDUS Dataset (Complete)
- Priority 2 – 3 OPEN Forms
- Next meeting is scheduled for Dec 9 @ 4:00 pm (ET)

Attendance:

Name	Affiliation
Shauna Hillman	Alliance
Thalia Beeles	COG
Ginger Riley	CTSU
Judi Manola	ECOG
Laliberte	ECOG-ACRIN
Christina Warmington	Essex Management
Joe Martucci	Essex Management
Neesha Desai	Essex Management
Andrea Denicoff	NCI
Tina Taylor	NCI
Rebecca Paulus	NRG
Vanita Patel	NRG
Angela Smith	SWOG
Cathy Rankin	SWOG
Peter Clark	Theradex
Brenda Maeske	Westat
Vanitha Chockalingam	Westat