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NRDS Content Working Group
Tuesday November 17, 2015
Meeting Minutes

Agenda Topics

caAERS/OPEN Discussion

- Assumption – Groups will be using this information from OPEN used in Rave without changes?
  - Theradex – Peter: Agreed
  - ECOG – Judi: Yes
  - SWOG – Angela: Agreed
  - COG – Dan: We do not do anything with OPEN Demography. There is one thing, when the patient enrolls in OPEN, we push the initial demography into Rave but we have a strong reliance on a patient registry. We maintain a list of patients. To get onto a COG study, the patient must first be registered in the registry, and then added to the study. We have an automated process to update Rave from there.
  - NRG – Rebecca: We are fine with this.

- With some approved exceptions, groups will be using these elements from caAERS used in Rave without changes
  - Peter: I believe we said we could add additional fields if we need to collect more data?
    - Dianne: Absolutely.
  - Theradex – Peter: Then, yes
  - SWOG – Angela: Yes
  - COG – Wendy: Yes
  - ECOG – Judi: Yes
  - NRG – Rebecca: Yes
  - Alliance: Followed up with Alliance after the call and they voted Yes

Ongoing Checkbox Discussion

Peter: Ongoing flag usage on AE form – a checkbox with a value of 1 (checked) or 0 (unchecked). When an AE record is entered, the default will be to have the box checked, noting that the AE is ongoing until it is resolved. There should only be one AE record for the onset date and grade. There is no need to re-enter in the next cycles/courses if it persists.

- Dianne: This will be added as conditional, only under a clear, defined situation.
- Judi: We are considering using a single log form for all AEs, is that what you do?
  - Peter: Yes, but we only work with unsolicited events.
  - Dianne: Our intramural program has done that for a number of years and it works well for them.
  - Angela: We have cycle specific AE forms but we do not do solicited events
  - Rebecca: We also have cycle specific AE forms but are considering moving to a single log form. We may have some instances where we need the solicited events that may cause an issue.
- Judi: If they wanted to trigger the site for events (solicited events), it would set up rules to prompt the event.
  - Melinda: We had a proximity AE form at each level that could induce edit checks to ensure it was filled out correctly.

- o Angela: To have to go back to a previous cycle to figure out if something was available would not be ideal
- Peter: The way we do it in CTMS, we have the sites reenter the AE in each course. Within each course, there is a log that runs within the course. If the AE persists, we require they add it in each new course until it is resolved. When we presented that to Mike Montello, he thought it would be too heavy a burden, so the system will now be able to handle both types of treatment. One of the initial questions in the mapping utility (at the beginning of the study to show how your forms map into the CDR), there is a spot to note if each AE will be represented in each course or not. Those are the two methods that can be used.
- Judi: Does anyone have a log form that sits there and is perpetuated through the whole treatment period, instead of just each cycle folder?
  - o Angela: We do that for our late affects but during treatment we do cycle specific forms.
  - o Shauna: Are you trying to get to an accumulative AE Form?
  - o Rebecca: Our main concern with completion date, how do you make sure the sites are reporting the conclusion of AEs in a timely manner.
  - o Peter: That comes down to monitoring. There will be a report in this facility that shows all of the AEs that are persisting. The report is a way for anyone with access to the web reporting to see what is going on in a study (i.e. which AEs persist).
  - o Shauna: You lose the tracking ability if it is on a cumulative list. If you have a tracking form it will the center will be reminded every month. There is no good way of knowing how many cycles of evaluation you have.
  - o Peter: For those studies that utilize the web reporting, you can get a report every week for what is going on with the AEs and what is going on in each cycle.
  - o Shauna: The report is only as good as the data behind it. Someone may be on cycle 6 but they may have only reported through cycle 3.
  - o Judi: If you have a toxicity report form at the end of every cycle it could be an indicator.
- Gwen: For data management, do you not project out date-wise and missing data on a general time schedule?
  - o Shauna: Alliance does it one cycle ahead.
  - o SWOG: Angela – We only roll out one cycle at a time.
- Peter: I can ask Diana Vuli to provide an overview of the techniques we use for keeping track of the AEs.
  - o Shauna: If you have monitors, it may not be an issue, but we do not have monitors. We have data managers and they rely on overdue data reports when things are overdue.
  - o Rebecca: That is the same with NRG, it is my concern that there will be AEs sitting out there forever.
- ****Action Item –** Peter: I can send this out for the group for vetting/voting on as a conditional field.
  - o Judi: I would like to go back and review our existing fields.
  - o Shauna: We do not currently require a result date or an ongoing field. We require it added for each cycle; it is a snapshot in time and you collect it at that time in the treatment.
  - o Wendy: We do not collect the ongoing AE either.
  - o Angela: Please provide us something in writing so we can share what is being proposed so we can research possible gaps.
  - o Shauna: Is it a matter of how this needs to be collected or the question of whether or not we need to collect it in the future?

- o Peter: Yes, this information is already required for some and we are looking for how to best collect it. CTEP asked us to build these specific reports but Mike Montello wanted the group to discuss it.
  - o Dianne: It sounds like this committee may be the entry way to get to CTEP/Mike Montello.
  - o Ginger: The fields that Peter are speaking about are specific to CDR activity and full CDISC reporting; that is where the mandate would be.
- Angela: Those fields are not currently required, we are discussing adding it for the future.
  - o Dianne: That is correct.
  - o Judi: In CDUS it states that if an AE persists, it should only be added once unless it increases.
  - o Peter: Yes, that is the purpose of this checkbox, if the grade worsens, the original would need to be resolved and a new AE would be created.
  - o Angela: We do have a field that is similar for collecting this information.
- Judi: There may be existing data points that may require mapping
  - o Peter: If it provides the information as needed, that would likely be acceptable.

Open Items

- Ginger: For the data quality standards working group and the data quality portal (tied to the delinquency studies), we are going to provide an update with the data quality working group co-leads next week. They should be providing an update sometime after that point. We are working on piloting activities for CTSU studies; we want to remove any bugs prior to releasing to you. The other next steps is to define delinquency studies.
  - o Ginger: Whenever any action is taken for a form, a new record is created in an audit trail. Even a small study can have a significant trail of audit records. These need to be parsed through and there is a significant amount of work. We are working on possibilities to minimalize some of the effort while working on the pilot.

Next Steps

- Priority 1 – CDUS Dataset (Complete)
- Priority 2 – 3 OPEN Forms
  - o All agreed on the next steps
- Next meeting is scheduled for Dec 1 @ 4:00 pm (ET)

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Attendance:

Name	Affiliation
Shauna Hillman	Alliance
Dan Jameson	COG
Wendy Wong	COG
Ginger Riley	CTSU
Judi Manola	ECOG
Melinda Flood	ECOG-ACRIN
Christina Warmington	Essex Management
Neesha Desai	Essex Management
Dianne Reeves	NCI
Gwen Dean	NCI
Rebecca Paulus	NRG
Angela Smith	SWOG
Peter Clark	Theradex
Vanitha Chockalingam	Westat