

**NRDS Content Working Group
Tuesday September 22, 2015
Meeting Minutes**

Agenda Topics - DRAFT

CTSU Meeting Update – Neesha provided an update from the CTSU meeting.

NRDS Content Review Process – Neesha discussed the process for the final recommendations review. This review is not a final sign off, it is just a sign off for implementation. Final sign off will happen after the content has been tested. The review period will be from Wednesday September 23rd, 2015 to Wednesday Sept 30th, 2015.

Theradex Date Discussion – Peter spoke to the onset and resolved date fields on the AE and SAE forms and the impact on the CDR and Web Reporting Project. There is a push to have a “resolved” date. There was an option of providing the current cycle of the AE; the resolved date may be a cleaner way to go. The length of a time an AE exists is quite vital to understand how a drug is impacting a patient’s body, so it may be relevant in a scientific nature. The onset date really helps to better explain how long the drug has been in a patient’s system as well. In some studies this may be hidden or deactivated because it is not required for CTEP monitoring.

- Susan: For the safety monitoring that is done via web reporting, at some point a resolve date would need to be provided (or ongoing). If we have this onset and resolve date, how would the data entry be done? Our assumption would be to assume the AE lasted 2 cycles; there would be an onset date but no resolve date. Once the AE is resolved, the resolve date would be provided. If no resolve date is provided, the assumption is that it is ongoing.
- Katie: Early on, we did discuss how the system integrations are driving standards. These onset and resolve date fields are not the only fields that the Theradex tool is expecting. We have been looking for what the system is requiring and using those.
- Ginger: Early on, Mike Montello confirmed that the CDR requirements would not affect us and this working group. I have not been involved on the latest discussions, has this changed?
- Peter: Looking at the whole picture, not just CDR conversations, I think we have all seen a slight evolution in “implied” policy. In the last meeting on the CDR Mike has mentioned something about the resolve date and I noted I was in this meeting and Mike requested I bring it to this meeting.
- Susan: I think earlier on, we were expecting the Standard Forms would meet the needs of all, and it does, except for these two fields that CTEP feels are critical.
- Shauna: Is there a mandate? We may need a list of things that are coming up for safety monitoring. If they are not required, we typically don’t collect them. I am not sure why we are discussing these.
- Ginger: I wonder if the date fields, is it CDR or CDISC reporting driven.
- Peter: Currently they are not part of CDISC complete reporting but are not in CTEP. They are driven more by the SAE and systems. Those are having greater and greater impact because of their integration in RAVE. We are discussing not just the SAE but also including them on the AE form.

- Shauna: It is fine to include them on the SAE form but adding them on the AE form is asking the sites to fill in more data that is not required for science.
- Susan: It is necessary for safety monitoring; there may be different ways to represent the monitoring but CTEP needs to see the different courses of the AE. We can bump the issue to Mike and he can address it.
- Shauna: I appreciate that but they need to mandate it prior to this committee making it a standard for AE.
- **Susan: We can relay this back to Mike Montello.

Review NRDS AE and SAE Integration Final Recommendation – Gwen provided an overview of how to view/comment on the current spreadsheet.

- Yellow Highlight – Potential/proposed change
- Column Y Summary of Recommendation
 - Green – Approved (complete agreement)
 - Olive Green – Approved (not complete agreement)
 - Orange – Yet to determine actual abbreviations for value meaning
- There is a column for 2nd review notes (AE) and a column for reasoning/explanation of any change requested (AF)

Next Steps

- One week final review
- OPEN Demography

Attendance:

Name	Affiliation
Katie L. Allen Ziegler	Alliance
Shauna Hillman	Alliance
Dan Jameson	COG
Wendy Wong	COG
Ginger Riley	CTSU
Vanitha Chockalignam	CTSU
Judi Manola	ECOG-ACRIN
Christina Warmington	Essex Management
Neesha Desai	Essex Management
Gwen Dean	NCI
Dianne Reeves	NCI
Rebecca Paulus	NRG
Vanita Patel	NRG
Tina Taylor	SAIC
Peter Clark	Theradex
Susan Davey	Theradex