

**NRDS Content Working Group  
Tuesday March 8, 2016  
Meeting Minutes**

## **Agenda Topics**

**Recap on OPEN Review** – Neesha Desai discussed the due dates for the OPEN review

**CTSU AE Review Update** – Tina Taylor announced that the NCI co-leads have accepted the comments from CTSU for the AE recommendations. There were no major changes from CTSU.

**OPEN Implementation Workflow** – Neesha Desai provided a list of assumptions for the OPEN Implementation Workflow. Ginger walked through the OPEN Implementation Workflow

- This process workflow is only specific to the implementation of the OPEN content. The process will be modified based on the set of content.
- Process includes
  - 1 Pilot LPO that has their own backend system
  - 1 Pilot LPO that uses only Rave (By Rave, we mean the CTSU pushes OPEN does to Rave)
- The caDSR Registry Steward is that curator who is working with the NRDS Content, i.e. Content Steward is Gwen Deen, overall caDSR may be Dianne Reeves

### *Discussion*

- Ginger: We do not want a scenario where it is completed in one spot but the ALS document is not completed.
  - Dianne: Where will the templates be housed?
  - Ginger: They are shared on the collaboration portal on the CTSU website; they are currently denoted with a version but a date schema may sound good as well.
- Peter: I assume there is a process to ensure each LPO updates their Rave URL with the standard forms?
  - Neesha: Yes, the Policy WG has built a number of policies to ensure the LPOs have updated data

**CDUS Content Review** – Gwen Deen

- The group that if the element is arbitrary, then a short text string will be used.

### *Subject Enrollment Form*

- CDE ID – 2182728
  - Dose/Total dose of the investigational agent administered per course
    - Group wanted to change it into 2 questions: dose and total dose
- CDE ID – 3028750
  - Unit of measure/dose minutes
    - Going to need 2 codes, dose from total dose the units can be different.
    - Does dose mean dose level? Dose, dose level, total dose

- Total dose – total dose administered for that reporting period
- At Theradex there is usually only 1 instance for a course/cycle but can be more than one. They have a field called actual total dose but that corresponds to the singular dose and the calculated dose would be all the doses and they also have a planned dose level.
- **Action Item: Dianne and Gwen to review the NCI standards and see what is in CDUS now to identify a comprehensive set of standards.**
- CDE ID – 3368866
  - Gender
  - Change to the recommendations in OPEN
- CDE ID – 2192217
  - Ethnicity
  - Change to the recommendations in OPEN
- CDE ID – 58384
  - Method of Payment
  - Change to the recommendations in OPEN
- CDE ID – 797
  - MEDRA AE code – baseline abnormality type
    - No comments
- CDE ID – 2944515
  - Adverse Event Grade
    - Rebecca: Is this appropriate for the information that is being collected because this is tied to the baseline abnormality so it is not really an AE; for some studies it is a pre-existing condition. I feel like AE implies a side effect to a treatment
    - Peter – Agrees
    - Angela – Agrees – asking to change
- CDE ID – 2453202
  - Has an AE been submitted?
    - Change to a short text string
    - Update definition to take out AdEERs to NCI caAERS
- CDE ID – 3855577
  - Category Response
    - Use short text strings
    - Potentially add to this list
- CDE ID – 3855587
  - Response Confirmed Date/ Response (observed date)
    - Angela – the date of the best response will still be the date of the first response first confirmed
    - Depends on how you use the data
    - Include in the definition that this is based on how the protocol is written

## Next Steps

- Next meeting is scheduled for March 15 @ 4:00 pm (ET)

**Attendance:**

<b>Name</b>	<b>Affiliation</b>
Kristina Laumann	Alliance
Leon Kalbefleisch	COG
Wendy Wong	COG
Ginger Riley	CTSU
Melinda Flood	ECOG
Christina Warmington	Essex Management
Joe Martucci	Essex Management
Neesha Desai	Essex Management
Dianne Reeves	NCI
Rebecca Paulus	NRG
Gwen Deen	SAIC
Tina Taylor	SAIC
Angela Smith	SWOG
Cathy Rankin	SWOG
Peter Clark	Theradex