

**NRDS Content Working Group  
Tuesday May 10, 2016  
Meeting Minutes**

## **Agenda Topics**

### **Review CDUS Content**

- Assessment Feedback
  - Alliance: Hard to standardized – CDUS is very tumor driven and not all our studies are the same
- Observed Date
  - Alliance: Derived field, collects something similar but must meet CDUS reporting needs
  - Theradex: collects date of response and date of progression at each course, not sure if they need to map for CDUS collection.
  - COG: Collect date of relapse and is study specific
  - NRG – RTOG Group statistician do not put response date through CDUS
- Assessments Comments
  - Alliance – don't send any comments, don't send to CDUS
  - Theradex – Don't send it to CDUS
  - ECOG-ACRIN – I am assuming this is the field on the trial comments, normally we only send in a comment as a result of a discussion with CTEP due to a specific exception they have asked for.
- Add into the policy document – you don't have to use all the fields, but if you use the fields they have to be used as the standard.
- Participant subgroup code
  - Theradex – All LPOs are using the same date format due to core configuration – Theradex wants to standardize this, interpret it is off all follow up. Agrees with Shauna to change the question text to be more specific
  - Rebecca – Definition of off study varies from study to study. I would argue this can't be standardized because of the varying nature of what it means to be off study.
  - Shauna – I think the whole point of standardizing means agree of the meaning – so we should not standardize this. Maybe we can name it to off study follow up end date
  - Gwen taking this back to see if we can do this.
  - Theradex – If this was standardized with the new question text, w
  - Rebecca – Study participation end date
  - Theradex – Study participation end reason for the previous one
- Is the participant ineligible for inclusion on this study – Do not standardize
  - Alliance: Means two different things
- Dose Modification
  - Theradex – we have a planned and unplanned. We have four options
    - Dose change from the previous course
    - No/yes/Yes Planned/Yes Unplanned/Unknown (from CDUS)
  - Rebecca – even if it was both planned and unplanned; combined responses rather than click all that apply
  - If we can get a change the PVs.
- Prior Therapy Type – Not standardizing

- ECOG – If the question is prior therapy type, that indications 1 type of therapy and the definition is a list of treatments, we think it should be 1 row per prior therapy. It would be easier for anyone collecting and extracting data. We have a log line with each line of therapy time
- Theradex – Shouldn't it be a check all that apply , we have that same format.
- SWOG – Add new question
- Alliance – collect in a log table, they only have to collect the number of legs they have
- COG – It is a log line and they have a drop down and if they check one, it will trigger the whole row.

### **Discuss Style Guide: Colon after Question Text**

- COG has been using a colon (:) after the term as our standard; we propose we use a colon after the term? Grammatically, it is appropriate to use the colon after the term (for attribution)
  - Gwen: The change would only be prospective, not for previous trials already in production. I do not remember seeing anything about this previously.
  - Wendy: This was something that was brought up recently and will require a full template change.
  - Peter: I have no problem keeping the colon as an option (alternate, not a preferred)
- Gwen: CTSU has already reviewed all of the data we have sent to them and have completed the impact of change for their system. If a change is made to the style guide, it will be a change to the preferred method.
  - Kristina: We would have to change all of our templates if the colon is a requirement
  - Melinda (ECOG-ACRIN): We do not use a colon and would not like to change. If it can be an alternate option for COG, that would be great
  - Rebecca (NRG): Same
  - Shauna (Alliance): Same
  - Peter (Theradex): Same

### **Next Steps**

- Kick off 2 week CDUS Review

**Attendance:**

<b>Name</b>	<b>Affiliation</b>
Kristina Laumann	Alliance
Shauna Hillman	Alliance
Justin Davis	COG
Phoebe Chang	COG
Wendy Wong	COG
Melinda Flood	ECOG-ACRIN
Christina Warmington	Essex Management
Joe Martucci	Essex Management
Neesha Desai	Essex Management
Rebecca Paulus	NRG
Vanita Patel	NRG
Gwen Deen	SAIC
Tina Taylor	SAIC
Peter Clark	Theradex