NIH NATIONAL CANCER INSTITUTE

NRDS Content Working Group
Tuesday May 3, 2016
Meeting Minutes

Agenda Topics

Project Recap – Neesha Desai announced a clarification from the last meeting that the OCI does not truncate PVs regardless of the number of characters.

- Mike: We are trying to take a minimalistic view on what we are standardizing. We never said they are just for integration. Not going to standardize everything, this is the activity where we can come to some agreement on it. We have to get to what are going to be the things we are going to standardize.
- Shauna: Why are we trying to standardize it? We need a rationale or reason.
- Mike: There are many benefits of standardization. The first benefit is integration. Second are the important reasons for the end users in the field. They need consistency in the field; operating as a network so it's easier for them to provide the data we need for clinical trials. We have also talked about cross study analysis for the future where we take information from 3 different trials and put the information together to do analysis. We should not be going down that pathway for all requirements but may be worthwhile for some of them.
- Andrea: It's easy to say let's standardize; it can be hard and cost can be prohibitive and we need to hear "these elements need to stay", "these are areas that are easy to do across the system", "here we don't get our bang for our buck."
- Mike: If others feel the same way, we should raise them. I can say with some confidence that if we go to NCI leadership with only standards for integration, we will get pushback.
- Rebecca: I agree we don't want to jeopardize the quality of the study for the greater good.
- Peter Clark: We agree with Shauna on the impact that changing the standard can have. We have standards that go back for over 30 years and all of our organizations have standards and we are trying to come up with something that makes it easier. We should always keep that mapping tool and there may be other creations of similar ways of creating a mapping that should be always considered instead of forcing a standard that will cause an undo issue in the most efficient way.
- Shauna: That is why I thought the mapping tool was there, it would allow us to keep our institutional standards, and now we are talking about both so just skeptical about the details but let's go through the exercise.
- Andrea: I was looking at widely published meta analysis and it had very critical fields and the mapping is very critical. In some disease areas it is hard to do so we should have mapping as a backup as much as possible.
- Dianne: Peter how do you make sure across groups that everyone is mapping in the same way?
- Peter: Maybe we need to make a cross group report; we need to have a validation to the mapping process.
- Dianne: That would also take human resources and time.

CDUS Reporting

- Shauna: If it's something that is being derived on the front end, we won't standardize it.
  - The group agreed
- Mike: Why can't you standardize it if you derive it?
- Shauna: We are not collecting on a CRF

- Peter: It could be standardized even if you don't do anything in it.
- Off study date –Do not standardize
  - Not typically collected on forms
  - Theradex collects
  - ACRIN collects those dates
- Date is easy to change
- If it's adding a new field, that ends up being more expensive
- Is patient ineligible?
  - We need someone from CDUS to interpret that
- Baseline abnormality flag
  - Group agrees to not standardize.
  - Alliance collects this
- Prior Therapy Type – Potential to standardize
  - Shauna – that would be a high cost one but each study may have a different need for the level of granularity
  - This study is only required for full CDUS, we are all colleting for reporting but collecting more details for analysis
  - It would just be adding a new question for us.
  - SWOG – It is a select all that apply so it is not a single field. We don't see the point of including options that we know won't apply to the study populations.
  - Potential but does have a lot of concerns attached it it.
- Dose Modification – Potential candidate for standardization because people have different values
  - How is everyone collecting this?
    - SWOG collected all
    - Same with Alliance
    - Same as COG
    - ECOG-ACRIN has both planned and unplanned
    - Andrea – If we have a treatment with multiple agents, we may need to add another options
    - Shauna – Dose modification question is agent specific…or is that different by groups
  - Total does of agent for this cycle course or visit: Good one for standardization
    - ECOG – sometimes we collect it like this, sometimes it's aggregate
    - Alliance – collects this, we collect by agent
  - Units of measure
    - Not all groups is collecting it
    - Theradex collects it and has a huge picklist
  - Adverse Events
    - SWOG – Derives
    - COG – Collects
    - Theradex – Collects
    - Alliance – Collects
    - NRG – Collects
    - ECOG - Collects
  - Verbatim term for baseline abnormalities
    - SWOG – collects only on registration trials – very rare
    - Theradex – collects
    - Alliance - collects only on registration trials – very rare

- AE event expedited

Next Steps

- Next meeting is scheduled for May 3rd, 2016

Attendance:

Name	Affiliation
Kristina Laumann	Alliance
Shauna Hillman	Alliance
Justin Davis	COG
Wendy Wong	COG
Ginger Riley	CTSU
Melinda Flood	ECOG-ACRIN
Neesha Desai	Essex Management
Andrea Denicoff	NCI
Dianne Reeves	NCI
Rebecca Paulus	NRG
Vanita Patel	NRG
Gwen Deen	SAIC
Tina Taylor	SAIC
Angela Smith	SWOG
Peter Clark	Theradex