

NRDS Content Working Group

Tuesday May 5, 2015

Meeting Minutes

Action Item	Who	By When
Send an email with instructions for next steps regarding the OPEN Demography content	Neesha Desai	5/07/15
Send out meeting minutes	Neesha Desai	5/08/15

Agenda Topics

Polling Exercise

- Smita: Are we trying to target a certain number of Common Data Elements (CDEs)?
 - Mike: We are not going to drive this by a magic number; we want to focus on what will be the most valuable to the National Clinical Trial Network (NCTN)/ETCTN.

Polling Exercise Votes

- Adverse Events
 - Alliance
 - COG
- Open Demography
 - Alliance
 - ECOG-ACRIN
 - NRG
 - SWOG
 - Theradex
 - COG
- Demography
 - Theradex
- Alliance and COG did agree that AEs may be a good place to start since the Serious Adverse Event (SAE) integration is on the horizon; there would be an opportunity to have an immediate impact on the sites that are going to implement soon. The only concern they had about OPEN Demography was that the integration is already done and any changes may require major changes to the OPEN system. They were not opposed to starting with OPEN Demography.
- Theradex voted to start with Demography. They did agree with the reasons to choose OPEN Demography however, when they compared the list to the Theradex CDEs, there were 4 CDEs that have coded Permissible Values (PVs) that are not all represented by the CDEs listed in the Demography section. Looking at how PVs might be represented internally would be a good place to start. They were okay with starting with OPEN Demography.

Additional Polling Discussions

- Tina: Does anyone collect any elements that are not in OPEN? One option would be to look at the both OPEN Demography and Demography to identify which CDEs we want to include with the OPEN Demography.

- Peter: Theradex does collect additional items beyond OPEN standards across all trials. We have one standards form that we have used for years and we continue to reuse for every trial. This is the enrollment form but we also have an administrative enrollment form; both forms are standards in all of our studies.
- Rebecca: NRG does collect the patient history form along with the OPEN and is standard across all trials. This was developed by the RTOG Patient Symptom Management committee and would not consider it for a greater group outside of NRG.
- ECOG-ACRIN, COG, Alliance and SWOG only collect OPEN Demography elements.
- Shauna: We should consider something like the patient history form out of scope for this activity because the majority of the group does not use it.
- The group agreed to focus on OPEN Demography since the majority of the group were using those elements.
- Katie: Why is Theradex using coded values while everyone else is not?
 - Peter: We have used this form for several decades. Our back-end database is used without those codes in mind and I believe the codes are based in a standard beyond just Theradex standards. It is more efficient to analyze in the back-end database.
- Shauna: Would there be any value if one group shares their package in Rave to this working group and see if there are any differences?
 - ECOG-ACRIN, Alliance, COG, SWOG, NRG and Theradex agreed they are use the ALS file as is.
 - Peter: We do not manipulate the files, all the data from OPEN goes into Interactive Web Response System (IWRS), where there is further configurations applied to it. The data from OPEN gets routed there into Standard Demography OPEN forms, as well as our own standard forms, so there are different PVs and coded values that IWRS handles. In our studies we have OPEN Demography forms but we do not make use of them because we have our standard enrollment form. We did not make any alterations to the ALS but we used IWRS to send the data in a different way to different places.
- Dianne: Does OPEN Demography meet everyone's needs? Is everyone able to do CDUS reporting?
 - Rebecca: For Clinical Data Interchange Standards Consortium (CDISC) reporting, there is manipulation on the back-end because everything comes over in character codes and needs to be changing for CDSIC reporting.
 - Shauna: If we are all using one standard, why would we map it to something different?
 - Smita: We do not touch the ALS file but we have the race and ethnicity entered and there is a mapping put in place to map it to one of our eight options for race in the OPEN Demography form. This happens beyond the ALS form.
 - Peter: One of the reasons why we have our own form is to meet our needs. We have the OPEN Demography form but that is not what we use to do our reporting, the codes we use in our enrollment forms are closer to what is needed in CDUS.
- Smita: If we all agree that CDUS reporting would like the OPEN Demography to be changed, is this working group where we would need to understand the changes and proposed the changes for the OPEN system?
 - Dianne: Yes, we would inventory what needs to be done and move forward with a set of recommendations.
- Tina: Our next step should be to confirm that the OPEN elements are meeting everyone's needs.
 - The group agreed that his approach sounds reasonable.

