

NCI CDISC Harmonization WG Meeting

Monday September 29th, 2019

Meeting Minutes

Agenda Topics

Neesha Desai reviewed the alternate question text workflow and discussed how LPOs should submit their requests.

LPO Discussion Items:

- PRO Fragment may be confused with Patient Reported Outcomes
 - Shannon explained that it is okay to have more than one abbreviation for the fragments as long as they make sense. The group agreed to use PROT and PRT. The fragments spreadsheet will be updated.
- Extensible Code Values (Slide 4, last bullet)
- **Question:** If a value is added to a code list, does that need to be approved for use by the Harmonization Working Group?
 - **Answer:** If you look through the code list and you do not find the term you need, the first thing you need to do is look at the extensibility attribute. If it says no, you cannot add any items to that list. One of two things is going on:
 - That code list could be lacking the term you need and we actually need to submit a request to CDISC to add it to the code list
 - You may need a different variable for the concept so people want to add values to the code list because they have always collected something in a certain way.
 - If the code list is extensible, and the value you need to add is the value you need to collect, you can add another value. The SME recommended that these types of values come to the Harmonization WG. Also recommend submitted those to CDISC.

RECIST Domain Overview

Shannon presented on 3 domains that would apply to RECIST: Tumor Identification (TU), Tumor Results (TR) and Disease Response (RS). These domains are in the current version of the SDTM IG. This presentation was a continuation from the Sept 9th meeting.

Next Steps

- Next Meeting: October 7th, 2019 @ 1:00pm EST

Reference Information

- All documentation will be posted on the [NCI CDISC Harmonization WG Wiki](#)
- [2019-09-09 Meeting Recording](#)