

## NCI CDISC Harmonization WG Meeting

Monday September 9<sup>th</sup>, 2019

### Meeting Minutes

#### Agenda Topics

Neesha Desai walked through the 11 Use Cases for the NCI CDISC Harmonization WG.

Shannon reviewed the Harmonization tool this group will be working with to harmonize the content on the roadmap.

- The group agreed to review the abbreviations tab and standardize that content along with the fragments to get a comprehensive list to use across the groups. The abbreviations tab was renamed to non-standard variables. Some of those items may move to the fragments tab.
- The abbreviations came off Theradex forms when they needed non-standard variables.

#### 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.

- **Question:** In reference to the slide with the tumor domains and responses, is this just a specific example where you are using group to put in response data rather than the tumor ID or can you do it either way?
  - **Answer:** You can do it either way, it depends on your study. If you need to assess disease response, you do it using Link Group ID in group.

The group agreed to continue reviewing the RECIST domains at the next meeting.

#### Next Steps

- Next Meeting: September 23<sup>rd</sup>, 2019 @ 1:00pm EST

#### Reference Information

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