

NCI CDISC Harmonization WG Meeting

Monday August 12th, 2019

Meeting Minutes

Agenda Topics

NCI CDISC Harmonization WG Overview

Neesha provided an overview of the NCI CDISC Harmonization WG

- The purpose of this group is to harmonize non-standard CDISC content into draft CDISC standards across the NCTN/ETCTN and submit to CDISC for standardization.
- The WG will work on the following deliverables
 - Prioritized list of content for CDISC Harmonization
 - Spreadsheet of proposed CDISC content to use across the LPOs
 - Best practices used during harmonization efforts

NCI CDISC Supplemental Questions Harmonization Review

- An update was made to box 1 in the workflow. The new language states
 - *LPO submits new supplemental question details to ncidiscsupport@nih.gov.*

NCI CDISC Harmonization WG Roadmap

- Neesha reviewed the draft roadmap. Each of the groups will review the roadmap and provide any additional content that needs to be added.
 - The group agreed to add the iRECIST forms to the roadmap
- CBIIT has been engaged in discussions regarding the Patient Reported Outcomes (PROs) and CDISC Harmonization activities. An update will be provided at our August 26th, 2019 working group call.

Questions

- *In terms of the RECIST forms, would the LPOs prefer to standardize the entire form across the NCTN/ETCTN or standardize some of the common questions?*
 - The majority of the group agreed that it would make the most sense to keep the mandatory, conditional and optional approach and standardize where we can.
- *ABTC does not use RECIST forms but they do need the measurement forms specific to their studies. How does that fit into this overall workflow?*
 - All forms that need to be reviewed and harmonized should be added to the roadmap and the working group will prioritize those items. Please submit those forms via the ncidiscsupport@nih.gov.

Action Items

- A suggestion was made to add the iRECIST forms to the roadmap and the majority of the group agreed. *Neesha will update the roadmap to include the iRECIST forms.*

Next Steps

- Next Meeting: August 26th, 2019 @ 1:00pm EST
- Each NCTN/ETCTN WG Representative needs to review the roadmap with their organizations and email the following information to ncicdiscsupport@nih.gov by August 19th.
 - Content/forms that need to be added to the LPO roadmap
 - Additional questions/study specific fields that need to be included in the harmonization work
 - Priority list of content from the roadmap to begin harmonization

Reference Information

- All documentation for this working group will be posted on the [NCI CDISC Harmonization WG Wiki](#)
- [2019-08-12 Meeting Recording](#)