

NCI CDISC Harmonization WG Meeting

Monday August 26th, 2019

Meeting Minutes

Agenda Topics

The NCI CDISC Harmonization WG reviewed 11 Use Cases for CDISC compliance/harmonization.

Use Case 1: Existing wording in pre-text in MH_MHSTDAT

It was suggested that an additional alternate text be added to the CDISC GLIB Field OID MH_MHSTDAT. The current CASH Model question text is “*What [is/was] the (intended/actual) [event/intervention] (start/admission) date ((of the observation))?*”

The following alternate was proposed, “*Initial Diagnosis Date*”, to be added to the CDASH Model Question Text.

LPO Discussion:

- Alliance and ECOG-ACRIN agreed with this approach
- CDISC SME: In both the SDTM and CDASH standards, it allows us to ask for this date and designated start date or define as a diagnosis or symptom onset date, however the diagnoses and onset date is in a different variable in SDTM. Right now the way the variable is structured, you would have to ask a separate question.

Proposal: Include the “Initial Diagnosis Date” as optional wording for MHSTDAT:

- Update for CDASH: *What [is/was] the (intended/actual) [event/intervention] (start/admission) date ((of the observation))?*
- Update for GLIB ALS Pre-Text: *What was the medical condition or event start date or initial diagnosis date?*

Use Case 2: Lesion Number

It was suggested to have an alternative question text for LinkID as Lesion Number

Proposal: Add an alternative question text to LinkID. “Lesion Number”

Use Case 3: Handling Clinical/Pathological AJCC v8 scoring

The group discussed ways to have meaningful descriptions of the AJCC v8 scoring rather than integers only. All the groups agreed as a whole the concept of this would be helpful however many groups have not gotten this far yet.

LPO Discussion:

- The groups agreed they would find it helpful if there way away to have more meaningful names for pathological staging.

- CDISC SME recommendation: One approach is to append the underscore and the test code value. This example follows the convention has been used in the TAUGs. There is another concept in CDASH and SDTM called METHOD to use and keep it closer to CDISC standards. Groups can pull the clinical and pathological into the method variable in this domain.

Proposal: This use case will be reviewed at a later time. The groups will use the CDISC SME's proposed methods and report back to the CDISC Harmonization WG on any additional feedback.

Use Case 4: Using Method of Evaluation vs Assessment on the Non Target RECIST 1.1 Form.

ECOG ACRIN is using Method of Evaluation on their forms. However during the focus group with Janice Knable (early 2018) all LPOs were opposed to using "Method of Measurement" and in the end the all agreed that "Method of Assessment" covered all assessment methods (such as clinical exam). The groups discussed if this was still the case. This is a potential that could be changed in CDASH.

LPO Discussion:

- SWOG: Already used Method of Evaluation because of CDASH
- Alliance: Using Method of Evaluation moving forward
- Other groups have not addressed this use case at this point.

Proposal: No next steps. ECOG-ACRIN will use Method of Evaluation moving forward.

Use Case 5: Using hidden fields for fixed units

In this use case, the site would see the value. It would be derived from a hidden field.

LPO Discussion:

- SWOG: Added a separate column and put in default values. In the case when there was only 1 question asked, they continued to use the fixed unit for the SDTM submission.
- Alliance: Suggested one thing to look out for with this approach. If anyone is going to create a 2nd field, you could easily forget to update the hidden field since units are not changed very often.
- CCTG: Instead of using the fixed units, CCTG suggested having the unit field visible and have it default to the value.
- SWOG: The perk of the fixed value is that visually it's in the right place on the form.

Proposal: No next steps.

Use Case 6: DSCONT – "Will the subject continue" in IG model wording is not specific enough

LPO Discussion:

- SWOG: As long it has the wording “Will the subject continue” in the question, SWOG is adding specificity for any given situation.
- CDISC SME: That approach can work but it is important to remember the meaning of the question is not changed.

Proposal: No next steps.

Use Case 7: Standardize Study Treatment Codes across LPOs.

ECOG-ACRIN suggested that having a standard of the CTEP agent codes may be helpful.

LPO Discussion:

- CDISC SME: Recommends it would be valuable having a standard representation of treatments in studies.
- CCTG: It always seems like it is an evolving dictionary with items being added or updated. We feel like that may pose a challenge to maintain.

Proposal: Each LPO needs to take back this proposal to their organization and discuss the benefits of having a standard representation of treatments to support consistency across studies.

Use Case 8 and 9: Use of Integers

Study has multiple arms and steps across multiple forms. If they use the same FIELD OID with a data dictionary, they cannot use that same FIELD OID in Rave with a subset of that same dictionary. Will need to create a new FIELD OID each time but the naming with the integer per the release notes does not make sense with this use case. (Example: EC_ECDECOD_01, EC_ECDECOD).

Formatting is different for a single OID. An example that we mentioned was if the “Dose” field formatting is different we need a new field OID. An example is one treatment agent should allow a max of 4 digits before the decimal and 2 after decimal (format example: 6.2) and another agent allows only for a max 3 digits and no decimals (format example: 3) you would need to have different OIDs: EC_ECDOSE, EC_ECDOSE_01.

The dictionary associated with the OID is different on different forms-- sites select different regimens for different arms/steps (and each one uses a different data dictionary).

LPO Discussion

- CTSU: For reuse of the dictionary, standard naming convention cannot end with an integer.
- ECOG-ACRIN: These are the Field OIDs. If you have an OID that you are using, you cannot use the same Field OID if the formatting or dictionaries are different. If you have two treatment forms and one has a specific type of formatting and

the other has a different one we have to have two Field OIDs because it carries over the same formatting. It's the same situation if you have Field OIDs that you use and dictionaries vary.

- Alliance: You can use the same Field OID if you have the same Var Nam. If you cannot change the format then you would need to use edit checks to set the field but would need a different Var OID.

Proposal: No next steps.

Use Case 10: Discontinued Date to allow Exposure End Date

Use Case 11: Data Dictionary with more meaningful names

LPO Discussion

- Alliance: The PID numbers are not intuitive and programmers and Rave builders would find it difficult to understand. It would be helpful to have a more global naming convention for dictionary names to be more meaningful.
- Theradex: We agree more meaningful would be very helpful, we can also continue on with no change implemented.
- ECOG-ACRIN: Agreed
- CCTG: Agreed
- SWOG: Agreed
- CDISC SME: If we are going to allow this, I would recommend rather than making up new names that we as much as possible use the existing names in the published CDISC submission value for the code list.

Proposal: NCI will discuss internally and propose a plan to address this concern. This is an item of great interest for the groups.

Next Steps

- Next Meeting: September 9th, 2019 @ 1:00pm EST

Reference Information

- All documentation will be posted on the [NCI CDISC Harmonization WG Wiki](#)
- [2019-08-26 Meeting Recording](#)