NCI CDISC Harmonization Working Group

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Agenda

- NCI CDISC LPO Use Case Recap/Updates

- Roadmap Review

- Review Harmonization Tool

- CDISC Harmonization

NCI LPO CDSIC Use Case Discussion

Use Case 1: Active

- **MH_MHSTDAT**: ECOG-ACRIN would like to propose some different wording for the pre-text and standardize that text across the groups if possible

CDISC GLib Field OID	CDISC GLib Pre-Text	CDASHIG Variable	CDASHIG Question Text	CDASHIG Prompt	CDASH Model Variable	CDASH Model Question Text	CDASH Model Promt	EA Proprosed Wording	Additional Comments
MH_MHSTDAT	What was the medical condition or event start date?	HSTDAT	What was the medical condition or event start date?	Start Date	STDAT	What [is/was] the (intended/actual) [event/intervention] (start/admission) date ((of the observation)?	[Intended/Actual] [Start/Admission] Date	Initial Diagnosis Date	Used on our Disease Description form

Proposal

Include the "Initial Diagnosis Date" as optional wording for MHSTDAT:

Next Steps

- Shannon will propose to CDASH: Update for CDASH: What [is/was] the (intended/actual) [event/intervention] (start/admission) date ((of the observation)?
- CBIIT to add an alternate question text: "Initial Diagnosis Date."
- Update CDISC Wiki: GLIB CDISC Best Practices
  - The LPOs have the option to use harmonized alternate question text that is in the NRDS context in the caDSR in place of the CDISC GLIB preferred question text as long as is it DOES NOT change the meaning of the question.

NCI LPO CDSIC Use Case Discussion

Use Case 2: Active

- ### Using Lesion Number vs LinkID

  - Confirm if LPOs rather use Lesion Number for the wording of the question vs what is in the ALS

    - Specified in draft Field Name

Proposal
Add an alternative question text to LinkID. "Lesion Number"

Next Steps
- Shannon will propose to CDASH
- CBIIT to add an alternate question text: "Lesion Number."
- Update CDISC Wiki: GLIB CDISC Best Practices
  - The LPOs have the option to use harmonized alternate question text that is in the NRDS context in the caDSR in place of the CDISC GLIB preferred question text as long as is it DOES NOT change the meaning of the question.

NCI LPO CDSIC Use Case Discussion

Use Case 3: Pending

- **Handling Clinical/Pathological AJCC v8 scoring**: There was a discussion about SCAT, RSCAT and RSSCAT and finding the need to have an additional approach to define which was clinical and which was pathological. How have other groups handled this?

  - RS_RSCAT   AJCC 8
  - RS_RSSCAT_Clin   BLADDER
  - RS_RSORRES_AJCC101   T Score
  - RS_RSORRES_AJCC102   N Score
  - RS_RSORRES_AJCC103   M Score
  - RS_RSSCAT_Path   BLADDER
  - RS_RSORRES_AJCC101_01   T Score
  - RS_RSORRES_AJCC102_01   N Score
  - RS_RSORRES_AJCC103_01   M Score

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.

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.

NCI LPO CDSIC Use Case Discussion

Use Case 4: Inactive

- **Method of Evaluation on Non Target RECIST 1.1 Form – Choices are Evaluation, Examination**: ECOG-ACRIN prefers Assessment - Discuss with the groups as this could be changed in CDASH

  - ECOG ACRIN is using Method of Evaluation on their forms. However during the focus group with Janice Knable (early 2018) where we spoke about irRECIST and RECIST there was a LONG discussion about the wording of this question.

  - 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).

  - That's why we are planning to switch to Method of Assessment. If Evaluation is in CDASH, would the groups agree to make this change?

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

NCI LPO CDSIC Use Case Discussion

Use Case 5: Inactive

- **Hidden fields for fixed units:** Discuss the benefit of hiding unit fields vs displaying them on the form.

  - ECOG ACRIN: When we expect one specific unit of measurement to go with a response (such as mg for dose) we usually just enter 'mg' into the fixed unit field in Rave.

  - However, this does not appear in the data set so we discussed possible having a separate hidden field for UOM with only that one unit in the data dictionary. This way it lives in the build but the sites do not see it and get confused (or complain about having to select from one dictionary option).

Proposal

No next steps at this time. Suggestions were made by groups for methods of handling this scenario and are included in the 8_26_19 meeting minutes.

NCI LPO CDSIC Use Case Discussion

Use Case 6: Inactive

- **DSCONT – "Will the subject continue" in IG model wording is not specific enough**

  - ECOG-ACRIN settled on EXCONTYN (does not exist in CDASH this is the field OID that Shannon suggested).

  - The wording on our form is "*Will the patient continue to receive protocol therapy*?". We felt that simply saying "*Will the patient continue*?" could be interpreted in too many different ways (*to more treatment, surgery, follow-up, etc*).

  - NOTE: this is on a trigger form so not sure if it needs to be compliant.

Proposal

As long as the wording includes "Will the subject continue" and the additional words do not change the meaning of the question, groups can add the specificity.

- Update CDISC Wiki: GLIB CDISC Best Practices
  - Any new alternate question text needs to be submitted to CBIIT for curation under the NRDS Context.

NCI LPO CDSIC Use Case Discussion

Use Case 7: Pending

- **Can we standardize a Study Treatment Code List across all LPOs?**

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.

NCI LPO CDSIC Use Case Discussion

Use Case 8: Inactive

- 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

Proposal

No next steps. Suggestions were made by groups for methods of handling this scenario and are included in the 8_26_19 meeting minutes.

NCI LPO CDSIC Use Case Discussion

Use Case 9: Inactive

- **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):**

Form Name	Form OID	Original Pre-Text	CDASH Field OID	New Pre-Text
Step 1 Treatment Regimen	ST1_TX_RGMN	Please indicate which treatment regimen the patient will receive in Step 1.	EC_ECDECOD_01	What is the planned Step 1 Treatment?
Step 2 Arm A Treatment Regimen	ST2_TX_RGMN_A	Please indicate which chemoRT regimen the patient will receive for Arm A in Step 2.	EC_ECDECOD_02	What is the planned Step 2 Treatment?
Step 2 Arm B Treatment Regimen	ST2_TX_RGMN_B	Please indicate which chemoRT regimen the patient will receive for Arm B in Step 2.	EC_ECDECOD_03	What is the planned Step 2 Treatment?

Proposal

No next steps. Suggestions were made by groups for methods of handling this scenario and are included in the 8_26_19 meeting minutes.

NCI LPO CDSIC Use Case Discussion

Use Case 10: Active

- **Discontinued Date is what ECOG will be using, potentially want to modify the allowed question for Exposure End:**

CDISC GLib Field OID	CDISC GLib Pre-Text	CDASHIG Variable	CDASHIG Question Text	CDASHIG Prompt	CDASH Model Variable	CDASH Model Question Text	CDASH Model Promt
DS_DSSTDAT	What was the Study Completion or Discontinuation Date?"	DSSTDAT	What was the Study Completion or Discontinuation Date?"	[Protocol Milestone/Disposition Event/Other Event Name] Date	STDAT	What [is/was] the (intended/actual) [event/intervention] (start/admission) date ((of the observation)?	[Intended/Actual] [Start/Admission] Date

NCI LPO CDSIC Use Case Discussion

- **Use Case 11: Data Dictionary with more meaningful names**
  - Example: "CDISC_SDTM_YES_PID6343337_V1_0F" to "NY_PID6343337_V1_0F"
    - The CM form can help illustrate why the Alliance would like to modify the dictionary names is to make them more "meaningful." We feel the dictionary names provide in the ALS do not provide any guidance to what the actually being collected.
    - CDISC_CDASH_CON_PID6400801_V1_0F
    - CDISC_CDASH_CON_PID6400807_V1_0F
    - CDISC_CDASH_CON_PID6401008_V1_0F
    - CDISC_CDASH_CON_PID6401063_V1_0F
  - The PIDs are not something our programmers or Rave builders are familiar with. My first thought is to name them as follows:
    - CMUnit_PID6400801_V1_0F
    - CMForm_PID6400807_V1_0F
    - CMFreq_PID6401008_V1_0F
    - CMRout_PID6401063_V1_0F
  - Renaming the dictionary names will help our programmers but also our Rave builders be more efficient.

LPO Use Case Dictionary Names

The CM form can help illustrate why the Alliance would like to modify the dictionary names is to make them more "meaningful." We feel the dictionary names provide in the ALS do not provide any guidance to what the actually being collected.
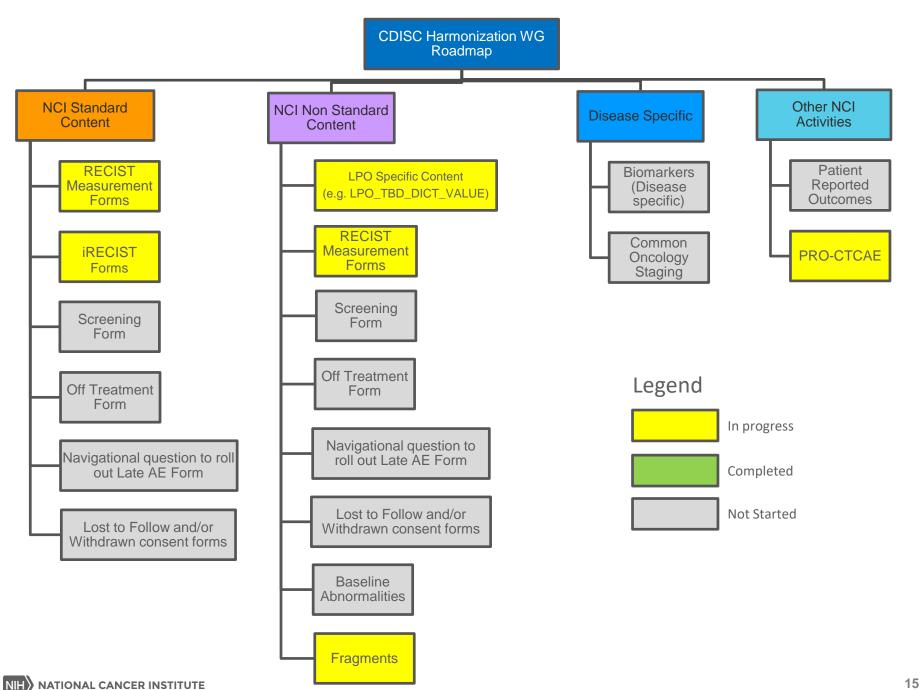
- CDISC_CDASH_CON_PID6400801_V1_0F

- CDISC_CDASH_CON_PID6400807_V1_0F

- CDISC_CDASH_CON_PID6401008_V1_0F

- CDISC_CDASH_CON_PID6401063_V1_0F

- Potential naming convention options:
  1) caDSR Value Domain Short Name + VD PID + Version #
  2) CDISC Submission value for the Controlled Terminology List + caDSR VD PID + Version #

Confirmed: Value domains curated for CDISC CDASH v2.0 content used the CDISC submission value for the Controlled Terminology List as the VD Short Name

VD PID	VD Version	VD Long Name	VD Short Name	EVS Code	CDISC CDASH Codelist Name
6400801	1.0	CDISC CDASH Concomitant Medication Dose Units Terminology Type	CMDOSU	C78417	CDISC CDASH Concomitant Medication Dose Units Terminology
6400807	1.0	CDISC CDASH Concomitant Medication Dose Form Terminology Type	CMDOSFRM	C78418	CDISC CDASH Concomitant Medication Dose Form Terminology
6401008	1.0	CDISC CDASH Concomitant Medication Dosing Frequency per Interval Terminology Temporal Frequency	CMDOSFRQ	C78419	CDISC CDASH Concomitant Medication Dosing Frequency per Interval Terminology
6401063	1.0	CDISC CDASH Concomitant Medication Route of Administration Terminology Type	CMROUTE	C78420	CDISC CDASH Concomitant Medication Route of Administration Terminology

Proposal

- LPOs have the option to update the VD long name + PID to the VD short name + PID
- This update would need to be managed directly in Rave, the OCI does not import the VD short name

CDISC Harmonization WG Roadmap

NCI Standard Content
- RECIST Measurement Forms
- iRECIST Forms
- Screening Form
- Off Treatment Form
- Navigational question to roll out Late AE Form
- Lost to Follow and/or Withdrawn consent forms

NCI Non Standard Content
- LPO Specific Content (e.g. LPO_TBD_DICT_VALUE)
- RECIST Measurement Forms
- Screening Form
- Off Treatment Form
- Navigational question to roll out Late AE Form
- Lost to Follow and/or Withdrawn consent forms
- Baseline Abnormalities
- Fragments

Disease Specific
- Biomarkers (Disease specific)
- Common Oncology Staging

Other NCI Activities
- Patient Reported Outcomes
- PRO-CTCAE

Legend
- In progress
- Completed
- Not Started

Next Steps

- **Next Meeting**
  - September 23rd 2019

- Continue reviewing content

LPO Management of Supplemental Questions Workflow

LPO identifies supplemental question for a protocol.

LPO reviews for a potential existing match.

Review CDISC Share

Review NCI CDISC Supplemental Questions List

No

Match Identified?

Yes

LPO utilizes existing question in CDSIC Share

Match Identified?

Yes

No

LPO creates question in Rave as per existing details, no changes are managed.

LPO utilizes that existing question in NCI Listing

Engage CDISC SME support as needed for supplemental question creation.

LPO creates the supplemental question in Rave, in harmonization with any applicable CDISC requirements/ considerations.

LPO implements the supplemental question for the target protocol.

LPO implements the supplemental question for the target protocol.

LPO submits new supplemental question details to CDISC Project team via ALS file within 15 business days of question implementation.

SUMBIT New Supplemental Questions to the CDISC Project team for inclusion into the **"NCI CDISC Supplemental Question Harmonization Review Process."**