NCI CDISC Harmonization Working Group

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Agenda

- NCI CDISC LPO Use Case Discussion

- Roadmap Review

- Review Harmonization Tool

NCI LPO CDSIC Use Case Discussion

Use Case 1:

- **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

NCI LPO CDSIC Use Case Discussion

Use Case 2:

- **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

NCI LPO CDSIC Use Case Discussion

Use Case 3:

- **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

NCI LPO CDSIC Use Case Discussion

Use Case 4:

- **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?

NCI LPO CDSIC Use Case Discussion

Use Case 5:

- **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).

NCI LPO CDSIC Use Case Discussion

Use Case 6:

- **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.

NCI LPO CDSIC Use Case Discussion

Use Case 7:

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

NCI LPO CDSIC Use Case Discussion

Use Case 8:

- 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

NCI LPO CDSIC Use Case Discussion

Use Case 9:

- **The dictionary associated with the OID is different on different forms-- sites select different regimen 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_ECDECOD01	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_ECDECOD02	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_ECDECOD03	What is the planned Step 2 Treatment?

NCI LPO CDSIC Use Case Discussion

Use Case 10:

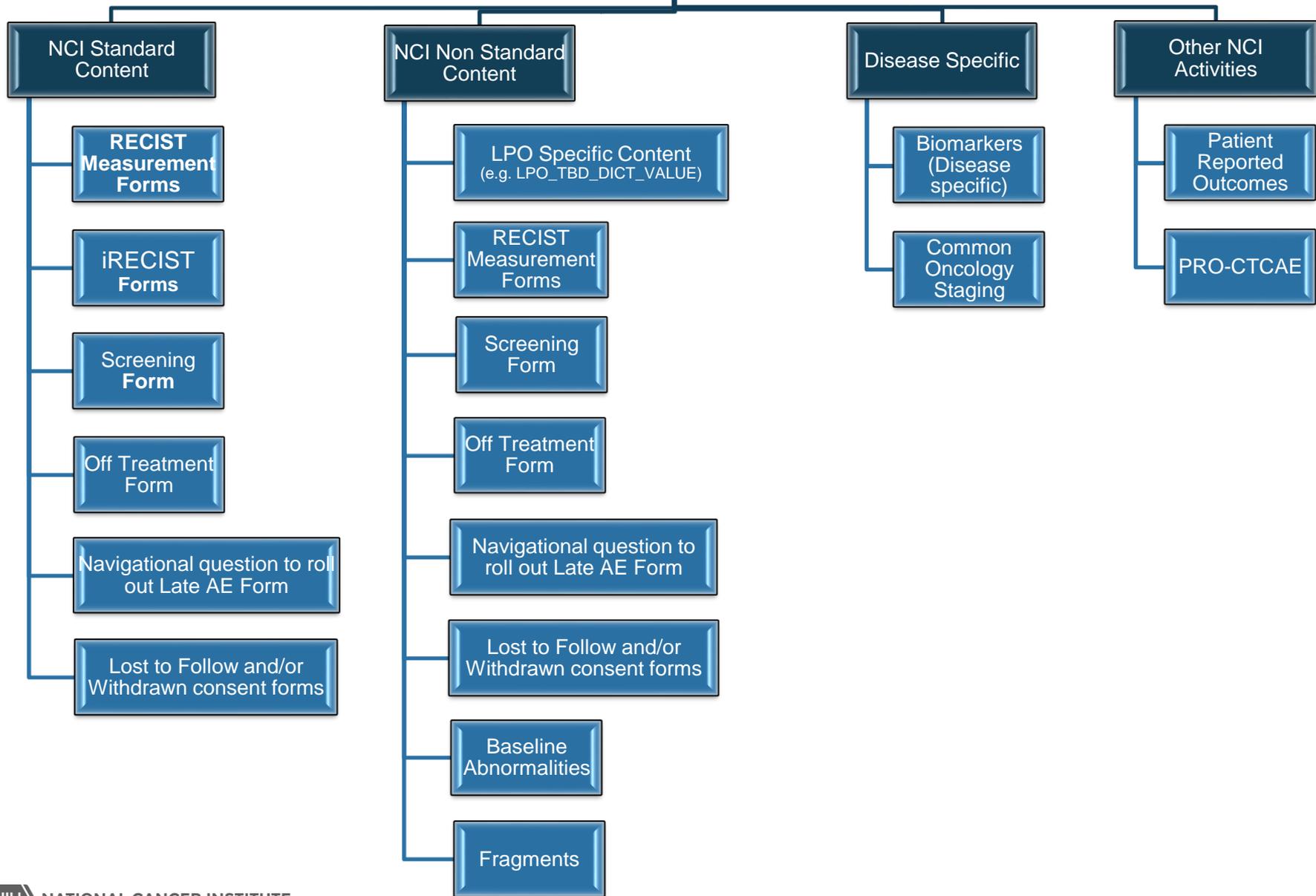- **Discontinued Date is what ECOG will be using, potentially want to modify the allowed question for Exposure End:**

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.

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

Next Steps

- **Next Meeting**
  - September 9th 2019

- Begin reviewing first set of content
- Verify you have access to the [NCI Implementation CDISC Wiki](#)