NCI CDISC Harmonization WG Meeting

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Agenda

- **CTEP CDISC Project Updates**
- **CDISC CT & Extensible Codelists Workflow**
- **Phase 3 NSVs/Supplemental Review**
- **Next Steps**

CTEP CDISC Project Update

- **ALS Release Schedule**
  - Updated target date v7.1 ALS release for LPO UAT: March 2022
    - Activities in process
    - This release will be managed per the CTEP CDISC Governance document

- **R6/R7**
  - CDISC Project Team is wrapping up R6 activities
  - R7 is specific to AJCC & is tabled until CDISC incorporates the 8th edition of AJCC

CDISC CT & Extensible Codelists Workflow

- **tbd**
  - tbd
- **tbd**
  - tbd

Phase 3 NSVs/Supplemental Review – THERADEX (1)

Variable	PreText/QT	Questions	CDISC HWG Review Notes
ASYNAM	Assay Name	Theradex • Provide details on the intent is for this variable? HWG Members • Provide feedback on similar use cases?	Theradex - created for the Theradex Covid-19 CRF, required field for this form; IDB & CTMB requested this field. Agree with CDISC SME's suggestion as a SUPPQ variable. (free text field) Part of most Theradex studies, would be difficult to change, migrated into legacy studies. PBTC – no comments at this time NRG – unlikely use, may follow SWOG's approach with a dropdown list; may use for ECs. SWOG – uses a dropdown list, using the lab category. CCTG - collect specimen collection type, do not collect assay name on their Covid-19 form. AMC – assays listed as individual fields with 'check all that apply' instructions. EA – may need to use in the future, no use case to date. COG – not collected at tis time, perhaps in the future there could be a use case. CDISC SME - CDISC HWG 09/08/2021 Discussion Theradex - created for the COVID 19 testing form, captures the name of the assay. Does a CDISC standard variable need to be created/identified by CDISC? CDISC SME - is this potentially a test code? No, this is the actual name of the assay. A SUPPQ does seem to be appropriate, depending on how this is used. There have been discussions regarding collection of assay names (within CDISC), but it has not progressed; this level of specificity is not often needed (for collection).
BESLPR	Slide Prep Type	Theradex • Provide any additional details on the intent is for this variable? HWG Members • Provide feedback on similar use cases?	Theradex – Specimen Transmittal CRF field; dropdown list used; standard field for all ETCTN studies that have specimen tracking activities; not typically submitted for reporting to FDA. PBTC - will discuss offline. NRG – no use case at this time. SWOG – not collected in Rave; data would not be submitted to the FDA. CCTG - not collected in Rave; data would not be submitted to the FDA; if collected would be partof their tissue bank & administrative. AMC – not collected in Rave; data would not be submitted to the FDA. EA – not collected in Rave; data would not be submitted to the FDA. COG - likely collected but not submitted to the FDA. CDISC SME – CDISC HWG 09/08/2021 Discussion Theradex - collected on the Specimen transmittal form for specimen tracking activities; dropdown field/PVs used, not a free text field.

Phase 3 NSVs/Supplemental Review – THERADEX (2)

Variable	PreText/QT	Questions	CDISC HWG Review Notes
BESPEC	Specimen Type	Theradex • Provide details on the intent is for this variable? HWG Members • Provide feedback on similar use cases?	Theradex - collected on the Theradex Specimen Tracking Enrollment CRF & derived to the Theradex Specimen Transmittal CRF; dynamic search list based on category selected, based on an enumerated CDE; administrative field, not submitted to FDA at this time; Theradex has seen a HUGE increase in (ETCTN/NCI) wanting to see specimen data over the past few years; this variable is noted by CDISC for TB TUAG. PBTC - CDE submitted specimen type, could consider using BESPEC. NRG – could consider using BESPEC; probably would not submit to FDA. SWOG – not collected in Rave; data would not be submitted to the FDA. CCTG - collected but use BECAT & BESCAT, could consider using BESPEC. AMC – could consider using BESPEC; currently using a dynamic codelist; not collected in Rave; administrative purposes. EA – correlative needs are managed outside of Rave; no current use cases for collecting specimen type; may be useful in the future. COG – use this variable for CDASH-compliant studies; not submitted to FDA. CDISC SME -
BESTRESP_SPD	Best Overall Response	Theradex • Provide details on the intent is for this variable? • How does this differ from RS? • Best overall response to what? HWG Members • Provide feedback on similar use cases?	Theradex - used for several forms; collects B.O.R. to a specific TX, while on study, etc.; pre-CDISC, PVs/ responses were few, post-CDISC implementation, the responses need to be more flexible; no change to existing responses, new responses are added as needed per protocol. Will review offline decision behind use of BE vs RS domain, any change would require major migration planning/activities. PBTC - not sure about use; this data is collected by the PVs are different. NRG – no use case at this time; Stats would derive this info; unlikely to be used. SWOG – similar use case; use an SDTM variable. CCTG – similar to SWOG, use RS domain & an oncology code table that was provided by CDISC (existing CT). AMC – would use this variable going forward. EA – similar use case, use RS domain. COG - similar use case, use RS domain, for overall response; do not usually collect best O.R. CDISC SME -

Phase 3 NSVs/Supplemental Review – THERADEX (3)

Variable	PreText/QT	Questions	CDISC HWG Review Notes
BSNCREAS	What is the reason the expected specimen collection was not completed?	Theradex • Provide details on the intent is for this variable? HWG Members • Provide feedback on similar use cases?	Theradex - used on Solicited Specimen Checklist CRF; protocol-specific PVs; 'NC' used for not collected; part of the Specimen Tracking system, not reported to the FDA. PBTC - no current use case; may not use this variable. NRG – would potentially use this variable admin., not to submit to FDA SWOG – not collected in Rave; data would not be submitted to the FDA. CCTG - using BSREASND at this time; will discuss offline. AMC – collecting something similar in Rave; administrative for protocol compliance. EA – not typically collected in Rave; may be collected outside Rave for correlative studies but not reported. COG - use a similar question, use 'REASND' and add the corresponding domain. CDISC SME -

Phase 3 NSVs/Supplemental Review – THERADEX (4)

Variable	PreText/QT	Questions	CDISC HWG Review Notes
CKBOX_ADD	Check box to add form	Theradex • Provide details on the intent is for this variable? HWG Members • Provide feedback on similar use cases?	Theradex – PBTC – NRG – SWOG – CCTG – AMC – EA – COG – Alliance – CDISC SME –
CKBOX_ALERT	Send Email Alert	Theradex • Provide details on the intent is for this variable? HWG Members • Provide feedback on similar use cases?	Theradex – PBTC – NRG – SWOG – CCTG – AMC – EA – COG – Alliance – CDISC SME –

Phase 3 NSVs/Supplemental Review – THERADEX (5)

Variable	PreText/QT	Questions	CDISC HWG Review Notes
CKBOX_ENDAT	Check if end date is the same as the start date.	Theradex • Provide details on the intent is for this variable? HWG Members • Provide feedback on similar use cases?	Theradex – PBTC – NRG – SWOG – CCTG – AMC – EA – COG – Alliance – CDISC SME –
CKBOX_SELECT	Reason for low pre-biopsy score result	Theradex • Provide details on the intent is for this variable? HWG Members • Provide feedback on similar use cases?	Theradex – PBTC – NRG – SWOG – CCTG – AMC – EA – COG – Alliance – CDISC SME –

Phase 3 NSVs/Supplemental Review – THERADEX (6)

Variable	PreText/QT	Questions	CDISC HWG Review Notes
CLIACNSTYN	Patient consented for CLIA sequencing assay for tumor profiling:	Theradex • Provide details on the intent is for this variable? HWG Members • Provide feedback on similar use cases?	Theradex – PBTC – NRG – SWOG – CCTG – AMC – EA – COG – Alliance – CDISC SME –
CLMTHIND	Was a specimen collected per method?	Theradex • Provide details on the intent is for this variable? HWG Members • Provide feedback on similar use cases?	Theradex – PBTC – NRG – SWOG – CCTG – AMC – EA – COG – Alliance – CDISC SME –

Phase 3 NSVs/Supplemental Review – THERADEX (7)

Variable	PreText/QT	Questions	CDISC HWG Review Notes
CNSTREAS	Reason for withdrawal of consent	Theradex • Provide details on the intent is for this variable? HWG Members • Provide feedback on similar use cases?	Theradex – PBTC – NRG – SWOG – CCTG – AMC – EA – COG – Alliance – CDISC SME –
CNSTREAS_OTH	Other reason for withdrawal of consent	Theradex • Provide details on the intent is for this variable? HWG Members • Provide feedback on similar use cases?	Theradex – PBTC – NRG – SWOG – CCTG – AMC – EA – COG – Alliance – CDISC SME –

Phase 3 NSVs/Supplemental Review – THERADEX (8)

Variable	PreText/QT	Questions	CDISC HWG Review Notes
COHORT	Cohort	Theradex – PBTC – NRG – SWOG – CCTG – AMC – EA – COG – Alliance – CDISC SME –	Theradex – PBTC – NRG – SWOG – CCTG – AMC – EA – COG – Alliance – CDISC SME –
COURIER	Courier Name	Theradex • Provide details on the intent is for this variable? HWG Members • Provide feedback on similar use cases?	Theradex – PBTC – NRG – SWOG – CCTG – AMC – EA – COG – Alliance – CDISC SME –

Phase 3 NSVs/Supplemental Review – THERADEX (9)

Variable	PreText/QT	Questions	CDISC HWG Review Notes
CPYSHP	Copy Shipping Status	Theradex • Provide details on the intent is for this variable? HWG Members • Provide feedback on similar use cases?	Theradex – PBTC – NRG – SWOG – CCTG – AMC – EA – COG – Alliance – CDISC SME –
DEVTYPE	Device Type	Theradex • Provide details on the intent is for this variable? HWG Members • Provide feedback on similar use cases?	Theradex – PBTC – NRG – SWOG – CCTG – AMC – EA – COG – Alliance – CDISC SME –

Phase 3 NSVs/Supplemental Review – THERADEX (10)

Variable	PreText/QT	Questions	CDISC HWG Review Notes
DSICVERS	Informed Consent Version	Theradex • Provide details on the intent is for this variable? HWG Members • Provide feedback on similar use cases?	Theradex – PBTC – NRG – SWOG – CCTG – AMC – EA – COG – Alliance – CDISC SME –
DVDESC	Description of Protocol Deviation	Theradex • Provide details on the intent is for this variable? HWG Members • Provide feedback on similar use cases?	Theradex – PBTC – NRG – SWOG – CCTG – AMC – EA – COG – Alliance – CDISC SME –

Phase 3 NSVs/Supplemental Review – THERADEX (11)

Variable	PreText/QT	Questions	CDISC HWG Review Notes
DVTERM_SPD	What was the protocol deviation type?	Theradex • Provide details on the intent is for this variable? HWG Members • Provide feedback on similar use cases?	Theradex – PBTC – NRG – SWOG – CCTG – AMC – EA – COG – Alliance – CDISC SME –
DXGRP	Primary Diagnosis Disease Group	Theradex • Provide details on the intent is for this variable? HWG Members • Provide feedback on similar use cases?	Theradex – PBTC – NRG – SWOG – CCTG – AMC – EA – COG – Alliance – CDISC SME –

Phase 3 NSVs/Supplemental Review – THERADEX (12)

Variable	PreText/QT	Questions	CDISC HWG Review Notes
DXVERIF	Diagnosis Verification	Theradex • Provide details on the intent is for this variable? HWG Members • Provide feedback on similar use cases?	Theradex – PBTC – NRG – SWOG – CCTG – AMC – EA – COG – Alliance – CDISC SME –

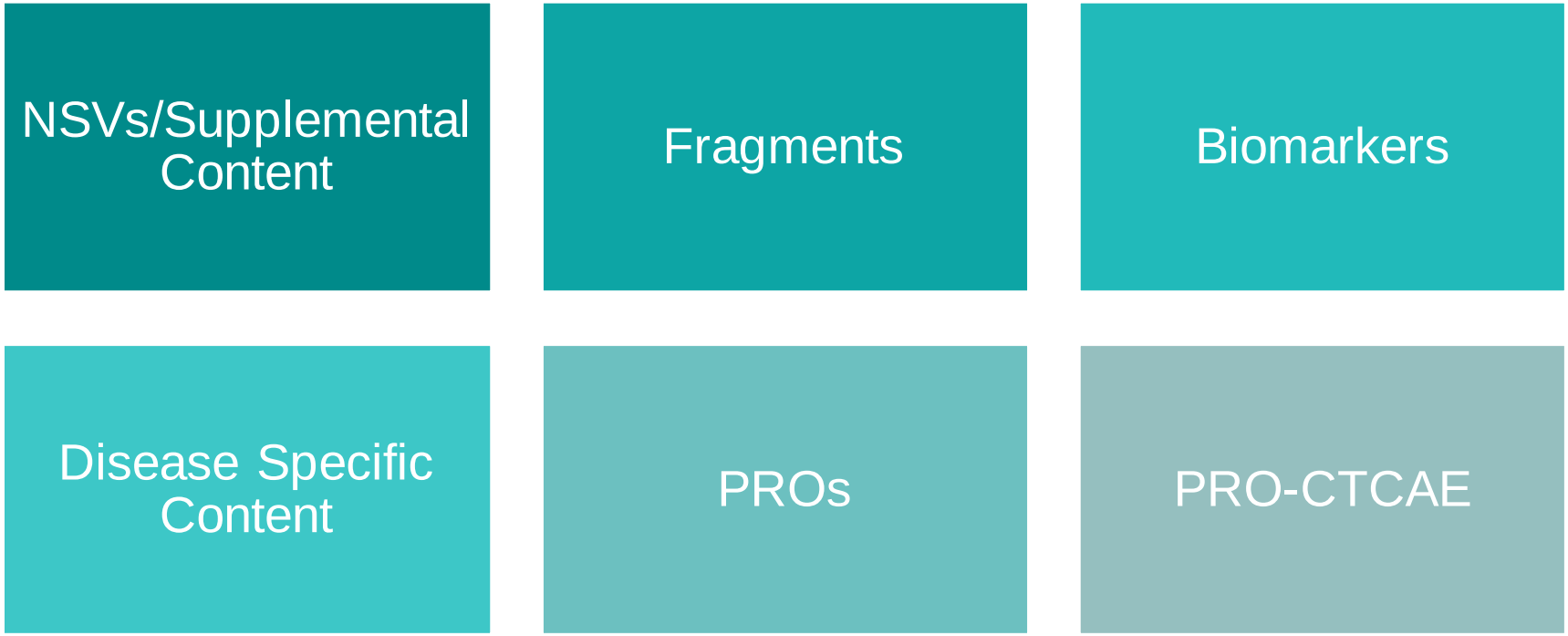
Next Steps

- **February 2022**
  - Ongoing NSV review/harmonization activities

Appendix

Phase 3 CTEP CDISC Standards Roadmap
CDISC & Sponsor-defined CT Use Case & Workflows
CTSU Standard Forms ALS Reminders
NCI CDISC Waiver Request Process & Examples
CDISC Harmonization Workflow
NCI CBIIT: CDEs for EC Forms Overview
CDISC Implementation Workflow
CTSU Change Matrix
eCRF Build Scenarios
LPO I.A.: Beta Release GLIB

Phase 3 CTEP CDISC Standards Roadmap



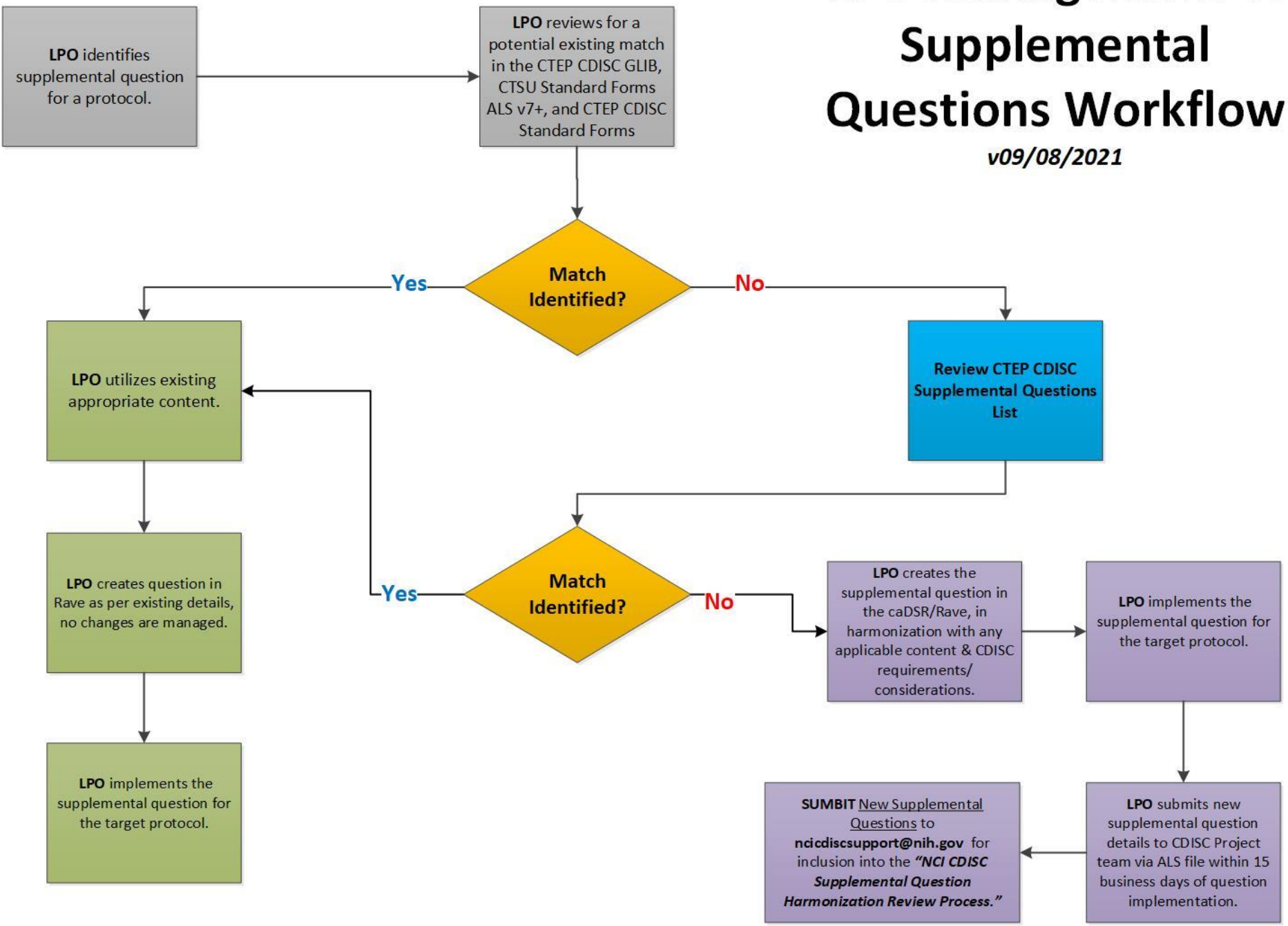
Phase 3 NSVs/Supplemental Content Review Process

- **Review Phase 3 content received from LPOs**
  - **Purpose**: Harmonize content across LPOs to package recommended standards for CDISC

- **Review Factors for NSVs/Supplemental Content**
  - Can each line item be reused across the majority of LPOs?
    - Harmonized items would be used for future collection if not currently collected.
    - Fields to Review
      - FieldOID
      - Draft Field Name
      - PreText/QT
      - Rave Help Text

LPO Management of Supplemental Questions Workflow

v09/08/2021



CDISC & Sponsor-defined CT Use Case & Workflows

Use Case: ensuring appropriate use of content (CDEs) for CDISC variables that have sponsor-defined CT. CDISC allows for sponsor-defined CT to be identified specific existing or custom/supplemental variables, whereas a CDE must be used as either enumerated or non-enumerated.

- **Sponsor-defined CT is identified for a new custom/supplemental CDISC variable, data entry will be managed via a dictionary list in Rave for this question/CDE**.
  - Verify _*SPD* is specified at the end of the new CDISC variable name;
  - Curate an enumerated CDE, specifying the new CDISC variable as the CDE Short Name;
  - Associate an enumerated Value Domain (VD) to the CDE that specifies the Sponsor-defined CT as PVs/PVMs;
  - Specify 'Other' as the PV/PVM if sponsor-defined CT isn't available during initial curation of the new CDE, add PVs/PVMs as available/verified;
  - Implement this CDE in Rave with dictionary values for the user to select from during data entry activities.
- **Sponsor-defined CT isn't identified for a new custom/supplemental CDISC variable, data entry will be managed via a free text field in Rave for this question/CDE.**
  - Verify _*SPD* is NOT specified at the end of the new CDISC variable name;
  - Curate a non-enumerated CDE, specifying the new CDISC variable as the CDE Short Name;
  - Associate a non-enumerated Value Domain (VD) to the CDE (no sponsor-defined CT/ no Permissible Values (PVs)/ no PV Meanings (PVMs);
  - Implement this CDE in Rave as a free-text field for the user to specify the requested data during data entry activities.

CTSU Standard Forms ALS- *Reminders*

- CTSU Central Study ALS details
  - Houses custom functions (CFs) needed for CTSU integrations
  - Allows for updates to be made without requiring LPO migration activities
  - Maintained by CTSU for all LPO urls except for the Alliance Rave url
    - CTSU does not have access to the Alliance Rave url
    - Alliance manages/ maintains Central Study updates for their url
- CDISC CTSU Standard Forms must be used as-is
  - Questions should not be removed
  - Questions can be added as needed by LPOs
- CTSU is working with multiple LPOs individually on integration issues
  - Patches are applied as needed across LPOs for common issues
  - Patches are applied as needed per issues identified by an LPO
    - as per LPO-specific Rave study build
  - CTSU will post challenges/issues/resolutions details to the Collaboration Portal

NCI Requirement- *Waiver Request Process*

- Send email to ncicdiscsupport@nih.gov
- Specify the following information in the email:
  - Protocol #
  - OEWG Date
  - Initial Production Date
  - New Production Date (if known)
  - Waiver Request Details

Send | To... | NCI CDISC Support <NCICDISCSupport@nih.gov>

Cc...

Subject | NCI CDISC Waiver Request - {insert LPO}

{insert LPO} is requesting a waiver for the study specified below:

Protocol #	OEWG Date	Initial Production Date	New Production Date	NCI CDISC Waiver Request Details
{insert protocol}	*{insert date, mm/dd/yyyy}*	*{insert date, mm/dd/yyyy}*	*{insert date, mm/dd/yyyy}*	*{specify details regarding why the waiver is being requested, including cause of delay, considerations, etc.}*

NCI Requirement- *Waiver Request Examples*

- Examples:
  - Acceptable waiver request: Study with an OEWG date of 12/1/19 whose activation is delayed due to drug supply until 3/15/20.
  - Unacceptable waiver request: Study with an OEWG date of 2/1/20 whose activation is delayed due to drug supply until 3/15/20. This study should have been built with the intention of meeting the original CDISC implementation date.

CDISC Harmonization Workflow *v06/25/2019*

1) LPO submits new supplemental question details to CDISC Project team via ALS file within 15 business days of question implementation.
2) CDISC Project team adds the new supplemental question to the **CDISC LPO Supplemental Question Listing**[1].
3) CDISC Project team prepares and submits the supplemental questions (partial or no match) to the CDISC Harmonization Working Group (WG).
4) CDISC Harmonization WG reviews, standardizes and harmonizes the supplemental question/s.
5) CDISC Project team prepares a supplemental questions review request for submission to CDSIC.
6) CDISC Project team submits and tracks review requests to CDISC.

Footnotes

1. *The **CDISC LPO Supplemental Question Listing** is a document created and maintained by the NCI CDISC Project team. This document will specify:*
   a. *Supplemental questions that have been recently created and implemented by an LPO for a specific protocol;*
   b. *Supplemental questions that have been harmonized/ standardized by the **CDISC Harmonization WG** and submitted by the CDISC Project team to CDISC for review.*

Project Updates (1)

- **CDISC Mailbox**
  - ncicdiscsupport@nih.gov
- **CDISC Wiki**
  - CDISC Webinars, Recording and Slides Posted
  - LPO FAQs
  - CDISC LPO Impact Analysis Feedback Posted
  - CDISC Harmonization WG Meeting Materials

NCI CBIIT: CDEs for EC Forms Overview

1. EC CDEs – *Inclusion/Exclusion Criteria*

- CDASH does not provide a variable for individual inclusion/exclusion questions
- Continue to curate these CDEs using your current process

TI – Examples for Trial Inclusion/Exclusion Criteria Dataset

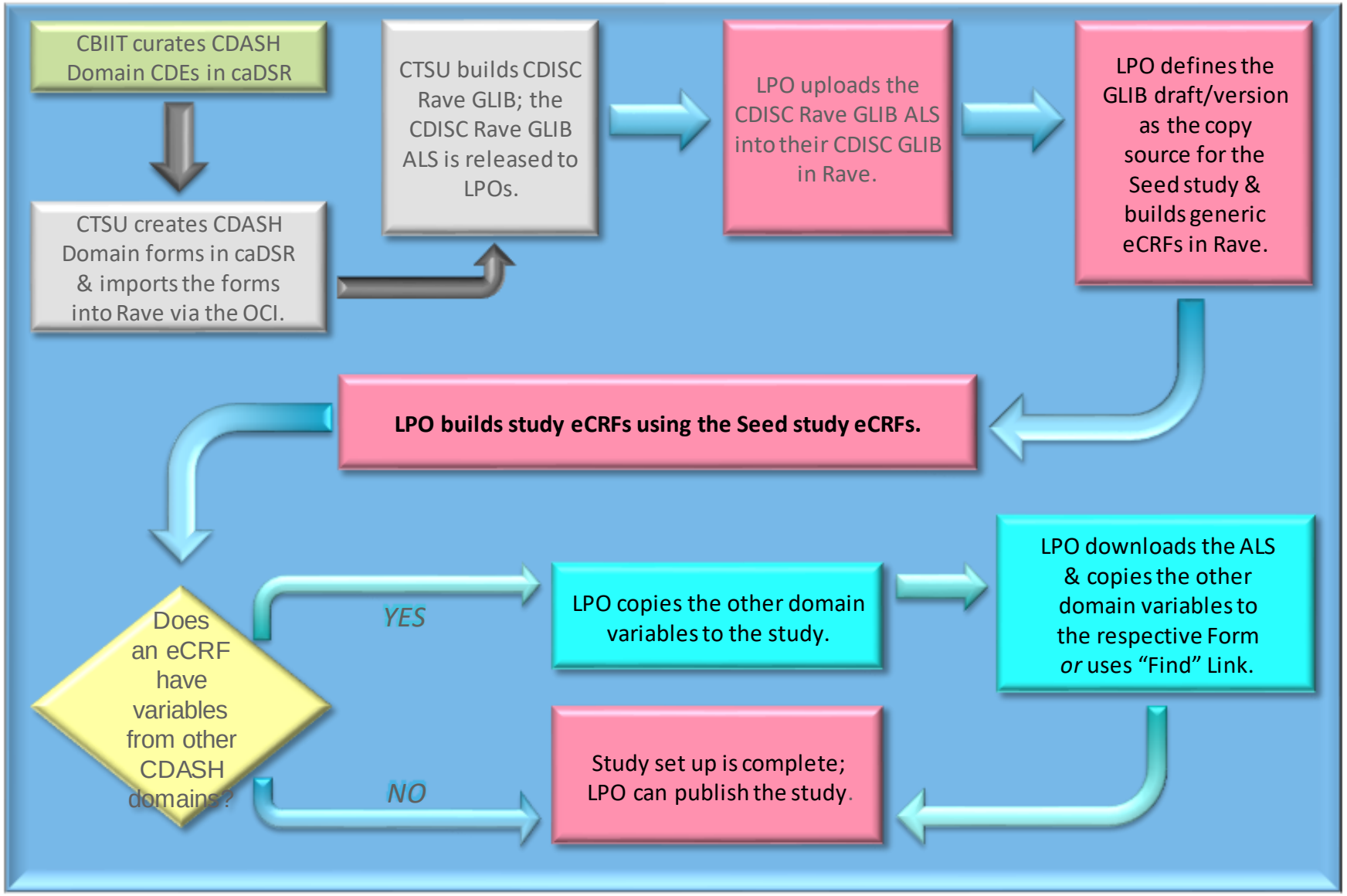
This example shows records for a trial that had two versions of inclusion/exclusion criteria.
Rows 1-3 show the two inclusion criteria and one exclusion criterion for version 1 of the protocol.
Rows 4-6 show the inclusion/exclusion criteria for version 2.2 of the protocol, which changed the minimum age entry from 21 to 18.

Row	STUDYID	DOMAIN	IETESTCD	IETEST	IECAT	TIVERS
1	XYZ	TI	INCL01	Has disease under study	INCLUSION	1
2	XYZ	TI	INCL02	Age 21 or greater	INCLUSION	1
3	XYZ	TI	EXCL01	Pregnant or lactating	EXCLUSION	1
4	XYZ	TI	INCL01	Has disease under study	INCLUSION	2.2
5	XYZ	TI	INCL02A	Age 18 or greater	INCLUSION	2.2
6	XYZ	TI	EXCL01	Pregnant or lactating	EXCLUSION	2.2

2. EC CDEs – Supplemental Qualifiers Domain Questions

- NCI CBIIT team will curate CDEs for the LPOs requesting assistance please submit request(s) to the NCI CDISC Mailbox
- Will curate only EC Forms where questions are not already curated CDASH or Inclusion/Exclusion
- For curation we will need CDISC details – LPOs provide map to SDTM:
  - Variable label
  - Variable name
  - Data format
  - List of values (if enumerated)

CDISC Implementation Workflow



CDISC Rave Global Library: CTSU Change Matrix

Rave Attribute	caDSR/ OCI Attribute	CTSU CDISC Global library	Change Management
Form Name	caDSR Form Long Name *(e.g., DEMOGRAPHICS)*	CDASH Domain Name *(e.g., DEMOGRAPHICS)*	*<no change: same as caDSR>*
Form OID	caDSR Form Long Name *(e.g., DEMOGRAPHICS)*	2 letter CDASH Domain Name *(e.g., DM)*	**Update by CTSU**
Variable OID	Short Name of the CDE *(e.g., RACE)*	CDASH/SDTM Variable Name *(e.g., RACE)*	<no change: same as caDSR>
Field Name	caDSR CDE Long Name + PID + MajorV + MinorV *(e.g., Race PID6343384_V1_0)*	Variable Label + PID + MajorV + MinorV *(e.g., Race PID6343384_V1_0)*	*<no change: same as caDSR>*
Field OID	2 letter domain prefix + CDASH/ SDTM variable *(e.g., RACE)*	2 letter domain prefix + CDASH/SDTM Variable Name (e.g., RACE)	*<no change: same as caDSR>*
Field Label	Question Text *(e.g., Which of the following five racial designations best describes you? (More than one choice is acceptable.))*	Question Text or Variable label *(e.g., Which of the following five racial designations best describes you? (More than one choice is acceptable.))*	**Update by CTSU** ***Specify the Variable label for Field Labels without question text ***
Data Dictionary Name	caDSR Value Domain Long Name + PID + MajorV *(e.g., CDISC_SDTM_RACE_PID6343345_V1_0F)*	caDSR Value Domain Long Name + PID + MajorV	*<no change: same as caDSR>*
Data Dictionary Values-User Data String	Permissible Value Meaning (PVM) *(e.g., Native Hawaiian or Other Pacific Islander)*	NCI preferred term *(e.g., Native Hawaiian or Other Pacific Islander)*	*<no change: same as caDSR>*
Data Dictionary Values-Coded Data String	Permissible Value (PV) *(e.g., NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER)*	Submission Value *(e.g., NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER)*	*<no change: same as caDSR>*
Format- Date	char - $11	dd MMM yyyy	**Update by CTSU**
Format- Time	char - $10	24 hr HH:nn:ss	**Update by CTSU**
Format- Char (W/ Dictionary)	char *(may be either the max length of dictionary value or extendable value;; e.g., $100)*	char *(may be either the max length of dictionary value or extendable value; e.g., $100)*	*<no change: same as caDSR>*
Format- Char (W/O Dictionary)	char -$200	char -$200	*<no change: same as caDSR>*
Format- Numeric	num	num	*<no change: same as caDSR>*
Control Type	*(e.g., DropDownList)*	DATE/TIME update	**Update by CTSU**
SAS Label	*n/a*	Variable Label from SDTM; if no SDTM variable, use CDASH variable label	**Update by CTSU**
Auto-Query for Required data entry	*n/a*	SDTM -Required & Expected Variables CDASH - HR and R/C	**Update by CTSU**
Auto-Query for future Date	*n/a*	Set flag in the CDISC Rave GLIB ALS	**Update by CTSU** ***Applicable to all dates***

eCRFs Build Scenarios *(1)*

Rave eCRFs may have different build scenarios:

1) Variables from a **single domain**
2) Variables from **multiple domains**
3) Custom variables that do not map to CDASH/SDTM

1) Single Domain: All variables in an eCRF are from a single domain.

Example: Concomitant Medication (CM) domain

- Set the CDISC Global library as the copy source for the study.
- Identify the Domain variables needed for the CRF.
- Use copy wizard to select and copy the variables from the domain identified for eCRF build.
- Multiple eCRFs can be built using the same domain by changing the FORM OID during the copy process.

eCRFs Build Scenarios *(2)*

2) Multiple Domains: Variables in an eCRF are from more than one domain.

Example: an Exposure form with variables from the EX and AE domains

- Follow the steps specified in the *"eCRFs Build Scenarios: Single Domain"* slide to build an Exposure form with variables from the EX domain.
- Using the copy wizard, copy the required variables from the AE domain to the study draft.
- Add AE domain variables to an Exposure form:

Option 1

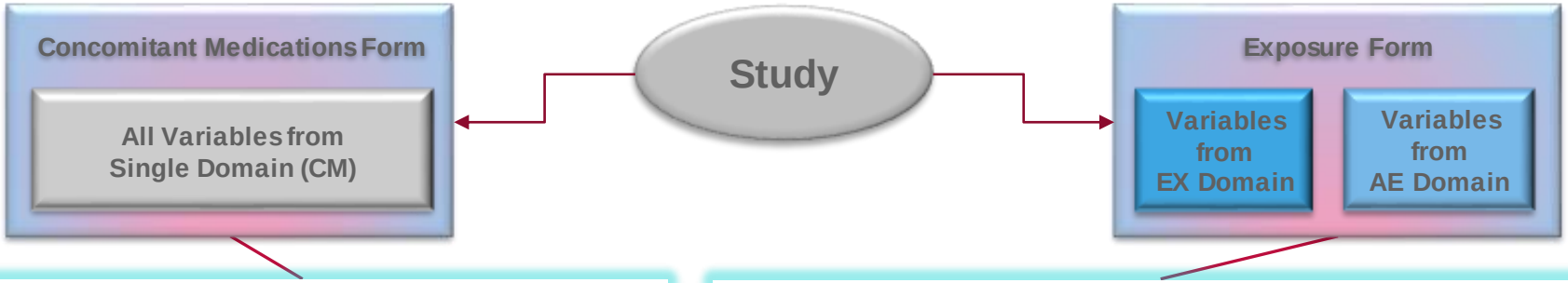
- Open the Exposure form; click add a new variable.
- Use the "Find" link on the variable definition screen to select the AE variable; click Apply to copy.

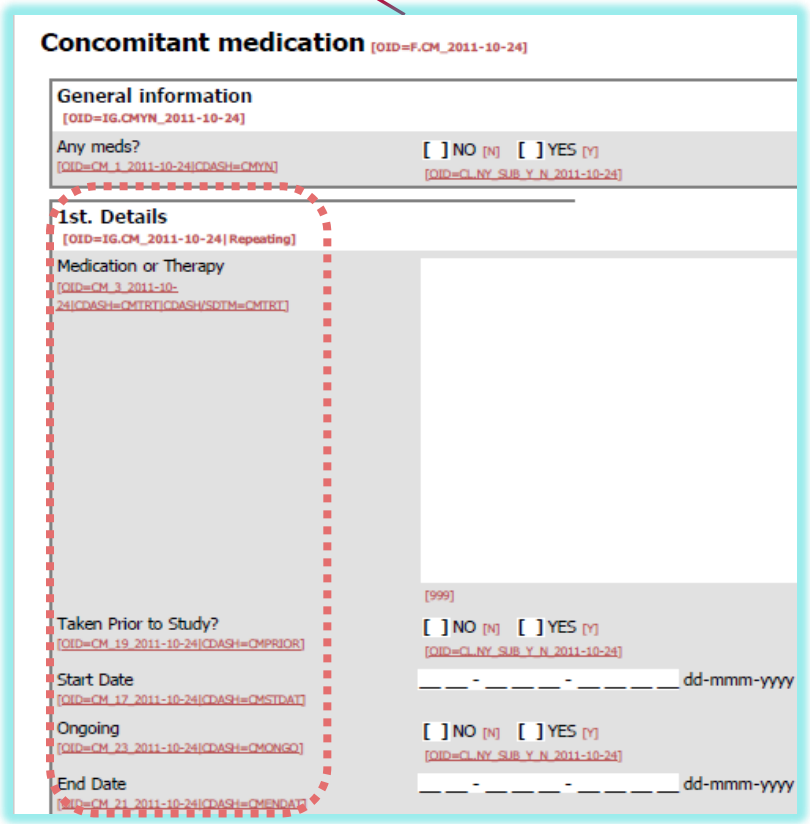
  Note: the "Find" link brings only the Variable OID, Format and Data/Unit dictionary, not the associated Field attributes.

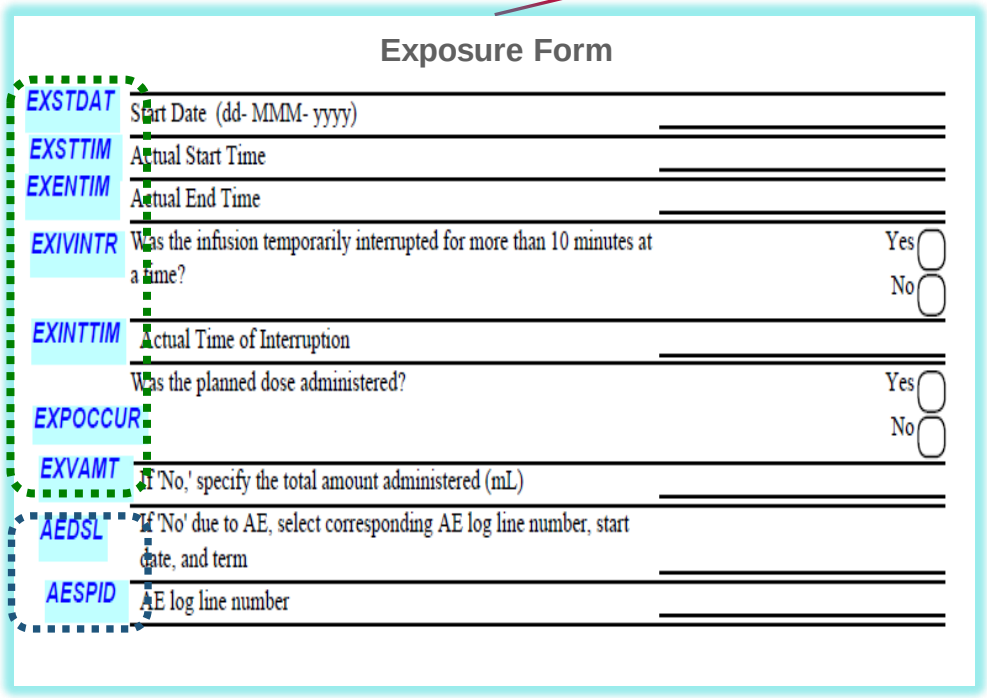
Option 2

- Download the ALS for the selected domains.
- Copy and paste the AE domain variables to the Exposure Form.
- Upload the ALS into Rave.

eCRFs Build Scenarios *(3-Examples)*







LPO Impact Analysis: Beta Release GLIB *(1)*

#	Document	LPO Findings/ Recommendations/ Questions	Decision
1	GLIB ALS	04/18/2019: I'm assuming a new release of the Controlled Terminology (CT) will be released prior to July. I wanted to confirm the final ALS release will contain the most up-to-date information. KL With the final release in July, will the GLIB and other ALS files be updated using the newest CDASH and SDTM controlled terminology packages?	CTSU will do an impact analysis (for CT Packages released by CDISC before July 2019) to understand the potential impact to our timeline. The intent it to provide documents as current as possible to CDISC releases/ updates; this must be done in consideration of the implementation timelines.
2	GLIB Release Notes: Section 3.2 Standard Conventions – Table 6	This table states that we cannot modify the Field OID. However, on the Variable Naming NVS webinar (3/28), Shannon presented several instances where it is expected and best practice to rename field OIDs in Rave for data collection purposes. In addition, the guide provides examples in 6.3 where it is OK/expected to change the field OIDs thus conflicting with the table. Please confirm Table 6 will be updated to reflect this.	05/02/2019 CDISC Integration FG: • LPOs can not change the field OIDs on Standard Forms • LPOs can change the field OIDS on Non-Standard forms if they have a strong reason to do so. "Standard Forms" applies to the CTSU Standard Forms ALS, "Non-Standard Forms applies to variables not specified in the CTSU Standard Forms ALS.
3	GLIB Release Notes: Section 3.2 Standard Conventions – Table 7	Given the needed updates to the Field OID to be specific (see situations/comment from 2), the SAS label should be modified for Rave data collection to ensure our programmers using CDASH Rave outputs can correctly identify the fields using the OIDs and Labels. Therefore, the SAS Label should be allowed to be modified when the Form OID is changed. (When data is transformed into SDTM format, the SAS Label can also be updated)	Maintain the same SAS label as in the CDISC GLIB for consistency across LPOs.
4	GLIB ALS	In the ALS, the Field name is the Variable Label + PID. Why the Variable Label? At the Alliance, we find having the Field Name match the Field OID + PID is much easier for specification writing, debugging and general viewing. (Medidata help guides state that in most cases, the Field name is the same as the Field OID.) As far as we understand, the Field Name isn't used for anything site facing or outputs. If the global ALS will not be changed, can the Alliance modify this?	No changes to the Rave Field Names in the CDISC GLIB ALS and CDISC CTSU Standard Forms ALS; the default naming convention will remain as-is, "the caDSR Long Name of the CDE + PID details". LPOs can use "the caDSR Long Name of the CDE + PID details" or choose to use "the caDSR Short Name of the CDE + PID details" as the Rave field name as needed. If the LPO chooses to use "the caDSR Short Name of the CDE + PID details" for the Rave field name, they are responsible for this update in Rave.

LPO Impact Analysis: Beta Release GLIB *(2)*

#	Document	LPO Findings/ Recommendations/ Questions	Decision
5	GLIB Release Notes: Table 6	For the User Data String, Table 6 states we must use the NCI Preferred term. However, CDISC training has stated we can use the NCI Preferred Term or CDISC Synonym. Please clarify which is correct.	LPOs can decide to use the NCI Preferred Term or the CDISC Synonym for the User Data String in Rave. If LPOs decide to use the CDISC Synonym instead of the NCI Preferred Term, they will be responsible for related study build activities and mapping activities for SDTM submission. The 'CDISC GLIB Release Notes' document will be updated to provide details for use of the CDSIC Synonym versus the NCI Preferred Term. The CDISC GLIB ALS will remain as is, no changes will be made to the User Data String and NCI Preferred Terms.
6	GLIB ALS	Why is the Data Dictionary Name not modifiable? Some dictionaries will be used across several fields; however, different sub-sets of responses will be needed for the questions. i. Rave does not allow us to subset the dictionary choices at the field level – a separate dictionary must be created ii. Example: NY. Sometimes Unknown or Not Applicable are not valid responses for a question iii. The Alliance would be open to a standard naming convention in this situation.	If authoring a form directly in Rave: LPOs should use the vetted CSC Data Elements Work Group (DEWG) naming convention (caDSR Value Domain Long Name + PID + MajorV + MinorV + _0F) for dictionary names and append an integer when subsetting a dictionary. If building a form in the caDSR/ using the OCI to import the form into Rave: the OCI will append an integer to the dictionary name when a dictionary is reused/ subsetted. Dictionary Names have been reverted to No changes will be made to the CDISC GLIB ALS. The CDISC GLIB Release Notes will be updated to include this naming convention for subsetted dictionary names.
7	GLIB ALS	When the GLIB is updated/versioned, can we get a detailed change log with the future releases?	A change log will be provided in the release notes for each updated GLIB release.

LPO Impact Analysis: Beta Release GLIB *(3)*

#	Document	LPO Findings/ Recommendations/ Questions	Decision
8	NCI/CDISC Best Practices Document	04/18/2019: In this section, it talked about all of these documents needed to be provided. I'm curious if there is any guidance to expected/required format and/or the level that we have to have prepared for CTEP-IND trials. We do not submit data directly to the FDA; I'm curious if we have to have annotated CRFs, and all these other documents that are listed for all trials. And if the trial has intent to submit to FDA, can we negotiate with our pharma partner on these. KL Section 4.3: What does this mean for us as LPO's? We are not translating all of these statements into what actions need to be done on Alliance trials. (Maybe the training is still coming?)	All CTEP IND studies activated on/after 1/1/2020 must be CDISC compliant. CDISC Compliance is highly recommended for studies that activate prior to the 2020 date. The CDISC SME to provide additional feedback at the "Overview of FDA Submission Process" Webinar on May 22nd, 2019.
9	NCI/CDISC Best Practices Document	Could a real life example/demo of the described best practices for the Eligibility Checklist Forms be provided? We're not following the workflows, when to curate/not curate, etc.	The CBIIT caDSR team presented the curation support/ process for eligibility criteria at the December Committee Meeting and an overview of this process at the April Committee Meeting.
10	NCI/CDISC Best Practices Document	Does NCI/CTEP submit data to FDA on NCTN trials? If so, study by study or aggregated across studies?	No decision required, NCI does not submit to the FDA.
11	NCI/CDISC Best Practices Document	Throughout the entire document, please be specific what CDISC compliant means. CDASH, SDTM, ADaM, etc. a. Additionally, our understanding from previous meetings is that the requirement is to be CDASH compliant only. We understood that it is up to the LPOs discretion and negotiations with the Pharma partner on SDTM programming. Please be specific in the document about whether we are referring to CDISC-CDASH or CDISC-SDTM.	The FDA requirement is SDTM. the NCI requirement is CDASH. CDASH compliance makes SDTM compliance easier to achieve. CDISC PM to review and update the NCI CDISC Best Practices document as needed to ensure clear communication of the NCI requirement for CDASH compliance.

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