NCI CDISC Implementation Committee

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Agenda

- COVID-19 Form Status and Potential Harmonization/Standardization
- CDISC Updates
- LPO CDISC Status Update

NCI CTEP COVID-19 Impact Analysis Purpose

- Determine if there are opportunities for standardization and harmonization for COVID-19 content across the NCTN.
- Understand the issues/risks from an LPO and site perspective.
- Identify differences in question/answer sets across the NCTN.

LPO Process COVID-19 Form Implementation

Consensus on question and answer sets

- No time for consensus across LPOs
- Provided a workspace space to share forms
- Provided CDISC SME COVID-19 webinars

Develop Rave CRFs

- Each group built they own CRFs in Rave
- Easier step in the implementation process

Implement forms in active trials

- Difficult step in the implementation process due to Rave migration activities
- Groups have 3 options: Manual, Master Study or Medidata Script Utility Script

LPO COVID-19 Implementation Approaches

Approach	Description	Pros	Cons
Migration (Manual)	LPOs create the COVID eCRFs and push into Rave.	No change in workflow for the site users. No new study invites for the site users	Complicated study amendment process that involves the study data migration Time consuming
CTSU Master Study	LPO sets up master study in Rave and CTSU will invite all the site users to enter data in the master study.	LPOs do not need to go through complicated study migration activities Long term value with similar collection of uniform data across many studies	Training for sites Workflow changes at sites Amendments to master study will be complicated
Medidata Script Utility Script	Allow customers to deploy their own COVID-19 form to a live study via Medidata Script.	Simplest approach No study migration needed Will address cons related to CTSU Master Study Can make updates to the COVID form as needed	Cannot support more than 1 COVID-19 Form. Tool is not available yet (June 1) No communication plan on potential solution.

LPO Migration Solutions

NCTN	Approach
ECOG-ACRIN	Waiting on Medidata Script Utility Script
SWOG	Waiting on Medidata Script Utility Script
CCTG	Migration (Manual)
NRG	Rave deviation feature
Alliance	CTSU Master Study

NCI CTEP COVID-19 Standardization/Harmonization

- Majority of questions were similar with minor differences in how they were asked:

	Alliance	SWOG	ECOG-ACRN	CCTG	NRG
Question	Was the participant tested for COVID-19?	Was a COVID-19 test performed?	Has the participant received positive results from COVID-19 testing?	Has the patient been tested for COVID-10?	Asked as protocol deviation
Response	Check Box	Check Box	Check Box	Check Box	
Response Type	Y/N	Y/N	Y/N	Y/N	

- Limited cases where specific Groups asked specialized questions

NCI CTEP COVID-19 Impact Analysis Considerations

- LPOs will have to repeat the implementation/migration process if a new form is harmonized.
- Significant amount of time and resources have already been spent on migration for some LPOs.
- Impact on LPOs that have already implemented the forms in many of their trials and are capturing data.

NCTN Feedback

NCTN	Feedback
ECOG-ACRIN	
NRG	
CCTG	
SWOG	
Alliance	
COG	

CDASH CDISC Public Review: ADaM Conformance Rules v3.0

- The definitions within the ADaMIG) versions 1.0, 1.1, and 1.2 and ADaM Structure for Occurrence Data (OCCDS) version 1.0 include specific guidelines and rules for defining and creating ADaM datasets.

- CDISC ADaM Conformance Rules may be used to validate datasets against a subset of these rules, which are objective and able to be evaluated unambiguously.

- **Review Instructions**
  - ADaM Conformance Rules
  - Instructions for Reviewers
  - Public Review closes **17 July 2020.**
  - You will need to log in or register for the CDISC Wiki to provide comments.
  - Register for the Wiki.

LPO Critical Status Updates- *05/27/2020*

LPO	Critical Update/Issue? *[Yes/No]*	Details
Theradex		
SWOG		
ECOG-ACRIN		
Alliance		
CCTG		
NRG		
COG		
PBTC		
AMC		

LPO Status Updates- *Theradex*

Current Update 05/27/2020	• NCI COVID Study activated, TRC10446 activated tomorrow, do have TRIAD but not CDISC compliant yet. Have additional studies that are almost done. Backlog and moving forward as they can.	
Current Issues/ Considerations	• Could be another protocol that should have activated in 2019 that may need a waiver, Peter will follow up offline	
Prior Update 04/22/2020	• *Gone to production with 10329 (first CDASH study). Working on 2 new COVID-19 studies. Currently working on 18 protocols, focus is on the 2 new studies and are hoping to make it CDASH compliant. TRC10446 (Treatment Study) activating early May. NCI COVID (Natural History) activating May 18th.*	
Seed Study	*Identified Y/N: Yes*	*Date Completed: ~11/25/2019*
Rave Study Build	*Initiated Y/N: Yes*	*Date Initiated: xx/xx/2019* • *(01/22/2020) Should have the first study built in Rave in a few weeks and then working on edit checks*
Central Study Status		• **No issues at this point, everything is working and will use that for future studies including the COVID studies.**
# CDASH/ SDTM harmonized CRFs:		• *All forms have been built and imported into Rave* • *Working on edit checks*
# CTEP IND Studies planned for Q1 2020 activation:		• 03/25/2020 update: tbd • *02/26/2020 update: 2 studies activated in February (5 pushed to production)*

LPO Status Updates- *SWOG*

Current Update 05/27/2020	• No major updates	
Current Issues/ Considerations	• Lessons learned has helped. Once data comes in may have additional issues.	
Prior Update 04/22/2020	• *Have 1 live study that is CDASH compliant. 4 are actively being built and 4 that are working on protocol development.*	
Seed Study	*Identified Y/N: Yes*	*Date Completed: ~01/xx/2020*
Rave Study Build	*Initiated Y/N: Yes*	*Date Initiated: xx/xx/2020* • *(01/22/2020) Should have the first study built in Rave in a few weeks and then working on edit checks*
Central Study Status		*Production Version Deployed*
# CDASH/ SDTM harmonized CRFs:		• *(01/22/2020) 28 forms fully mapped to SDTM and built in Rave, have 28 forms left*
# CTEP IND Studies planned for Q1 2020 activation:		• 03/25/2020 update: tbd • *02/26/2020 update: 1 study to activate in March 2020*

LPO Status Updates- *ECOG-ACRIN*

Current Update 05/27/2020	• Activated first CDSIC study (EA5191). EA5182 and EA8185 are next in the pipeline.	
Current Issues/ Considerations	• No Issues	
Prior Update 04/22/2020	• *4/10 study has an extension and scheduled for July. 2 that are competing EA5191 and EA5182 (May to July activation). Total of 3 more that have not started protocol development (1 is a registration study)*	
Seed Study	*Identified Y/N: Yes*	*Date Completed: ~April 2020 (EA8158)*
Rave Study Build	*Initiated Y/N: Yes*	*Date Initiated: ~09/01/2019*
Central Study Status	• **Discussing Central Study internally and will update next month**	
# CDASH/ SDTM harmonized CRFs:	• *All forms have been identified for harmonization, # to be confirmed* • *10 standard forms in seed study*	
# CTEP IND Studies planned for Q1 2020 activation:	• 03/25/2020 update: tbd • *02/26/2020 update: (Q2 activities) EA8185 seed study scheduled for April; 5191 scheduled for late May activation; 5182 scheduled for mid-July activation*	

LPO Status Updates- *Alliance*

Current Update 05/27/2020	• No major update. Have 2/3 studies built and pending activation.	
Current Issues/ Considerations	• No Issues	
Prior Update 04/22/2020	• *Finished study build for 1st two CDASH studies. Waiting activation for other reasons.*	
Seed Study	*Identified Y/N: Yes*	*Date Completed: 1/1/2020 (Alliance Global Library)*
Rave Study Build	*Initiated Y/N: TBD*	*Date Initiated: TBD*
Central Study Status	• **CTSU provides the Central Study ALS to Alliance; does not manage deployment activities.**	
# CDASH/ SDTM harmonized CRFs:	• *39 forms fully harmonized with CDASH with unit test completed* • *15 have been built in Rave, but only touched on edit checks, just started on custom functions* • *All forms have been harmonized with CDASH and built* • *Working on custom functions with the first three studies for CDASH study specific fields*	
# CTEP IND Studies planned for Q1 2020 activation:	• 03/25/2020 update: tbd • *02/26/2020 update: A081801 or A071702*	

LPO Status Updates- *CCTG*

Current Update 05/27/2020	• No major update. Working on the 2 trials and are moving forward. Working on the code tables and working with CDISC SME	
Current Issues/ Considerations	• No Issues	
Prior Update 04/22/2020	• *First 2 trials will start in May (delays due to COVID). GLIB are completed and dictionaries are 50% done for GLIB.*	
Seed Study	*Identified Y/N: TBD*	*Date Completed: TBD (Building Global Library first)*
Rave Study Build	*Initiated Y/N: TBD*	*Date Initiated: TBD (Working through Global Library and mock templates)*
Central Study Status		• **Do not use the central study**
# CDASH/ SDTM harmonized CRFs:		• *39 forms fully harmonized with CDASH with unit test completed* • *15 have been built in Rave, but only touched on edit checks, just started on custom functions* • *All forms have been harmonized with CDASH and built* • *Working on custom functions with the first three studies for CDASH study specific fields*
# CTEP IND Studies planned for Q1 2020 activation:		• 03/25/2020 update: tbd • *02/26/2020 update: (Identified Q2/Q3 studies)* - *MA40* - *OV27* - *HD11* - *PR21* - *First IND Trial in late 2020: AL6*

LPO Status Updates- *NRG*

Current Update 05/27/2020	• No major update • GY020 CDISC Study opened, CC005 in development and BR007	
Current Issues/ Considerations	• No Issues	
Prior Update 04/22/2020	• *4 studies in development*	
Seed Study	*Identified Y/N: Yes*	*Date Completed: TBD*
Rave Study Build	*Initiated Y/N: Yes*	*Date Initiated: ~March 2019*
Central Study Status	• *Production Version Deployed*	
# CDASH/ SDTM harmonized CRFs:	• *Every external form (~50) has been harmonized* • *internal forms are pending*	
# CTEP IND Studies planned for Q1 2020 activation:	• 03/25/2020 update: tbd • *02/26/2020 update: (targeted Q2 studies)* - *HN007* - *HN008* - *BN007* - *LU007*	

LPO Status Updates- *COG*

Current Update 05/27/2020	• 2 studies in pipeline and 1 is in the process to be put in form builder and curation • August/Sept for activation	
Current Issues/ Considerations	• *No major issues*	
Prior Update 04/22/2020	• *Working on 1 study to make CDASH compliant. Reviewing with builders and identifying variables.*	
Seed Study	*Identified Y/N: No*	*Date Completed: TBD*
Rave Study Build	*Initiated Y/N: No*	*Date Initiated: TBD*
Central Study Status		• **Central Study deployed for UAT Testing**
# CDASH/ SDTM harmonized CRFs:		• *TBD*
# CTEP IND Studies planned for Q1 2020 activation:		• 03/25/2020 update: tbd • *02/26/2020 update: {TBD- not present for February Committee Meeting}* • *01/22/2020 update: No studies planned for Q1*

LPO Status Updates- *PBTC*

Current Update 05/27/2020	• No change, CDASH workshop scheduled for next week. Protocol for study activation.	
Current Issues/ Considerations	• No issues	
Prior Update 04/22/2020	• *Do not have a new study for development, working on an amendment.*	
Seed Study	*Identified Y/N: No*	*Date Completed: TBD*
Rave Study Build	*Initiated Y/N: No*	*Date Initiated: TBD*
Central Study Status	• **Central Study has been deployed**	
# CDASH/ SDTM harmonized CRFs:	• *TBD*	
# CTEP IND Studies planned for Q1 2020 activation:	• 03/25/2020 update: tbd • *02/26/2020 update: TBD*	

LPO Status Updates- *AMC*

Current Update 05/27/2020	• Working on first study build, reviewing answers from support group feedback	
Current Issues/ Considerations	• Avg length of time to build and deploy a study: • SWOG (12 weeks for FDA timeline) – keeping protocol comments in mind	
Prior Update 04/22/2020	• *Have a call scheduled for next week. Goal will be to complete the first study build which will provide guidance on additional forms for compliances.*	
Seed Study	*Identified Y/N: No*	*Date Completed: TBD*
Rave Study Build	*Initiated Y/N: No*	*Date Initiated: TBD*
# CDASH/ SDTM harmonized CRFs:		• *TBD*
# CTEP IND Studies planned for Q1 2020 activation:		• 03/25/2020 update: tbd • *02/26/2020 update:* - *AMC107*

Appendix

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

CTSU Standard Forms ALS- *Status*

- v2.3 Non-CDISC CTSU Standard Forms ALS
  - No new version needed at this time (no v2.4 scheduled)
  - Feedback/technical updates – *pending*
  - Central Study ALS v2.3 updates – *pending*
  - Timeframe TBD
- v7.0 CDISC CTSU Standard Forms ALS – *no changes*
- v7.1 CDISC CTSU Standard Forms ALS – *pending*
  - Potential updates under review include
    - LPO-requested changes
    - Required technical updates
  - List of LPO-requested changes will be provided for LPO review
  - Corresponding new Central Study ALS v7.1 will be developed by CTSU
  - Timeframe TBD – *late 2020*

CTSU Standard Forms ALS- *v7.1 Planning*

- Projected Next Steps – *Timeline TBD, late 2020*
  - NCI PM receives & incorporates CTIS feedback
  - Focus Group finalizes review & decisions
  - NCI PM summarizes & prepares documentation for LPO-requested changes
  - LPOs review & achieve consensus for LPO-requested changes
  - CTSU manages technical updates development & testing
  - NCI PM verifies implementation plan details & release dates
    - CDISC CTSU Standard Forms ALS v7.1
      - Includes CDISC SME & NRDS compliance reviews
    - CTSU Central Study ALS v7.1
      - Includes upload to LPO Rave URLs

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

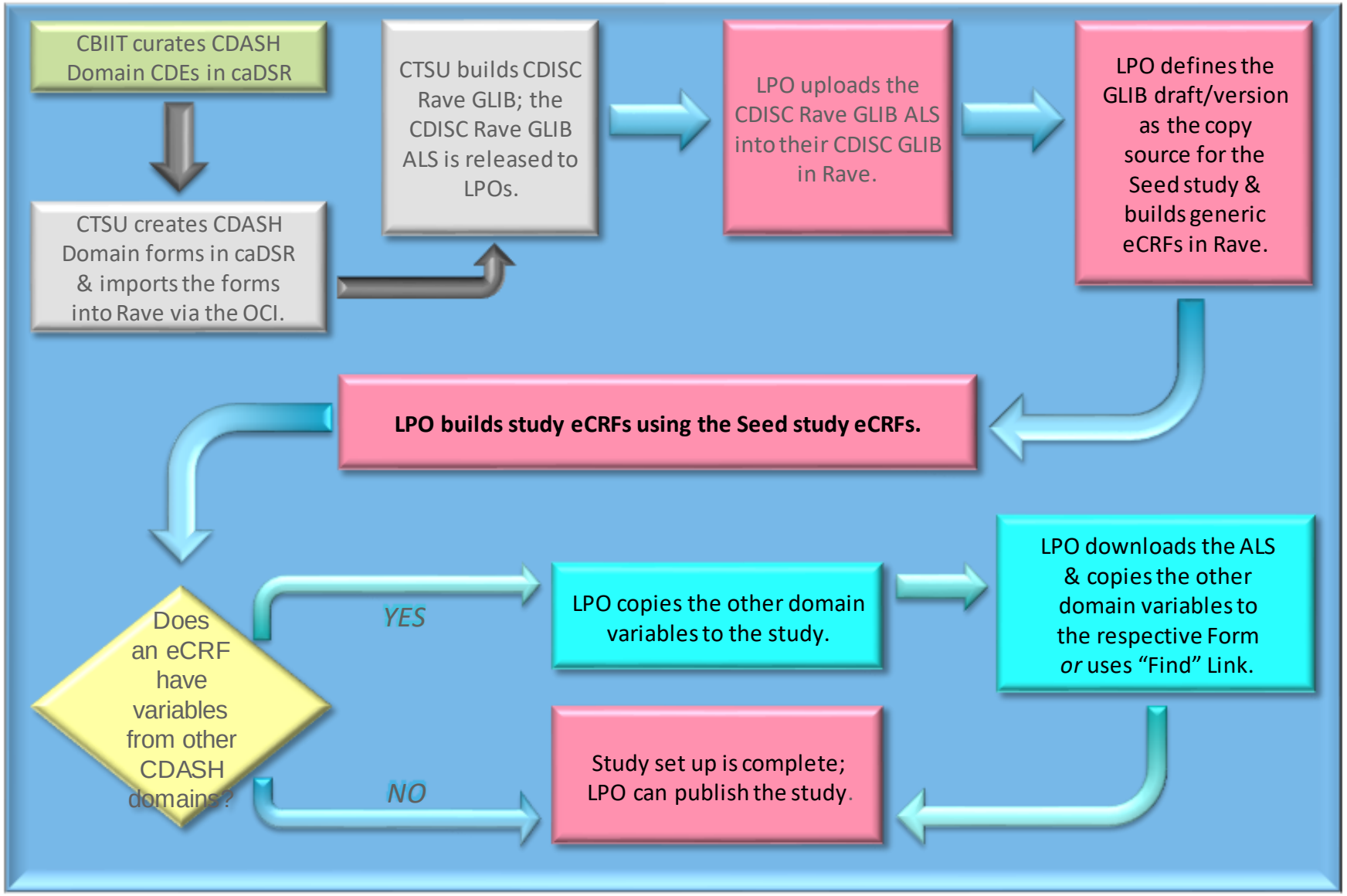
This example shows records for a trial that had two versions of inclusion/exclusion criteria.
Rows 1-3 show the two inclusion criteria and one exclusion criterion for version 1 of the protocol.
Rows 4-6 show the inclusion/exclusion criteria for version 2.2 of the protocol, which changed the minimum age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

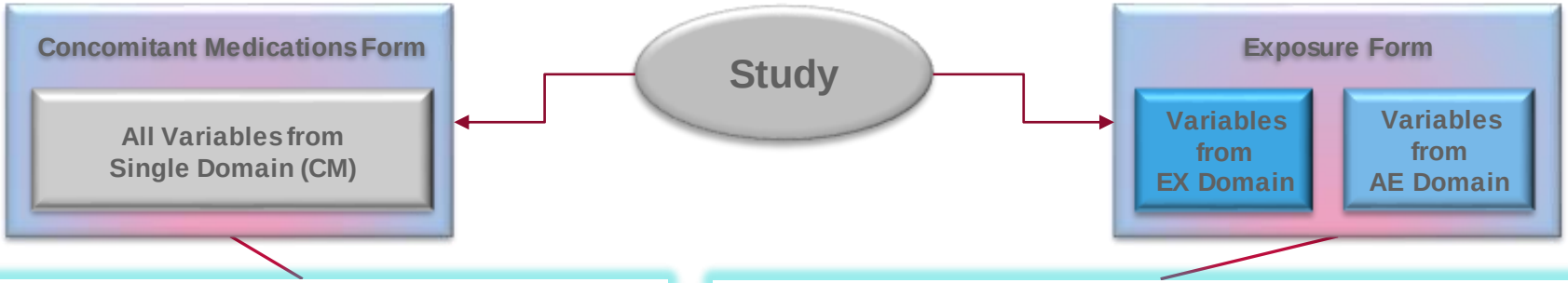
- Open the Exposure form; click add a new variable.
- Use the "Find" link on the variable definition screen to select the AE variable; click Apply to copy.

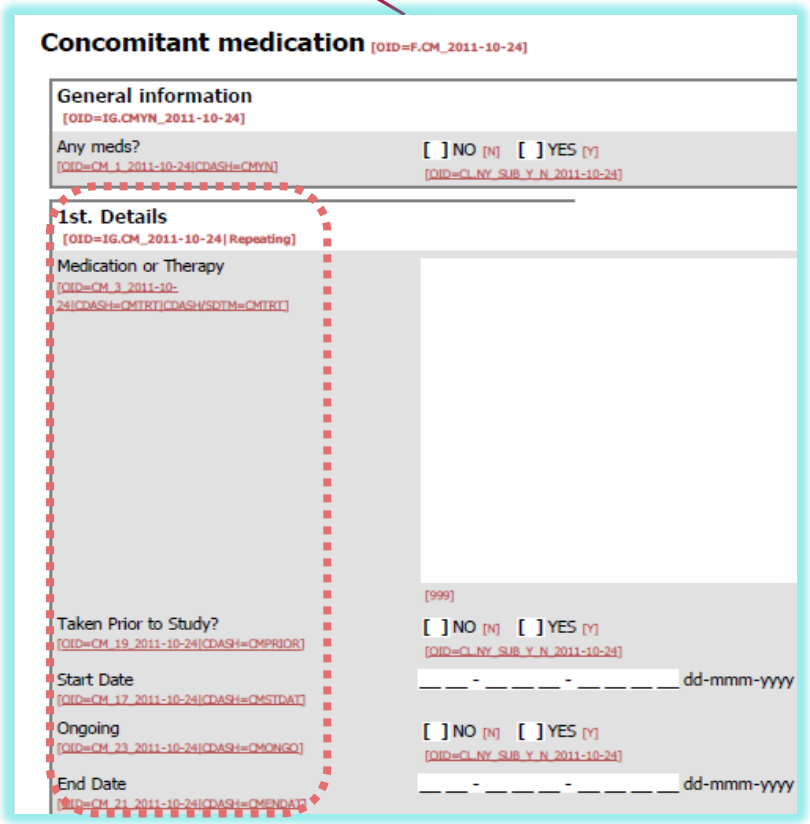
  Note: the "Find" link brings only the Variable OID, Format and Data/Unit dictionary, not the associated Field attributes.

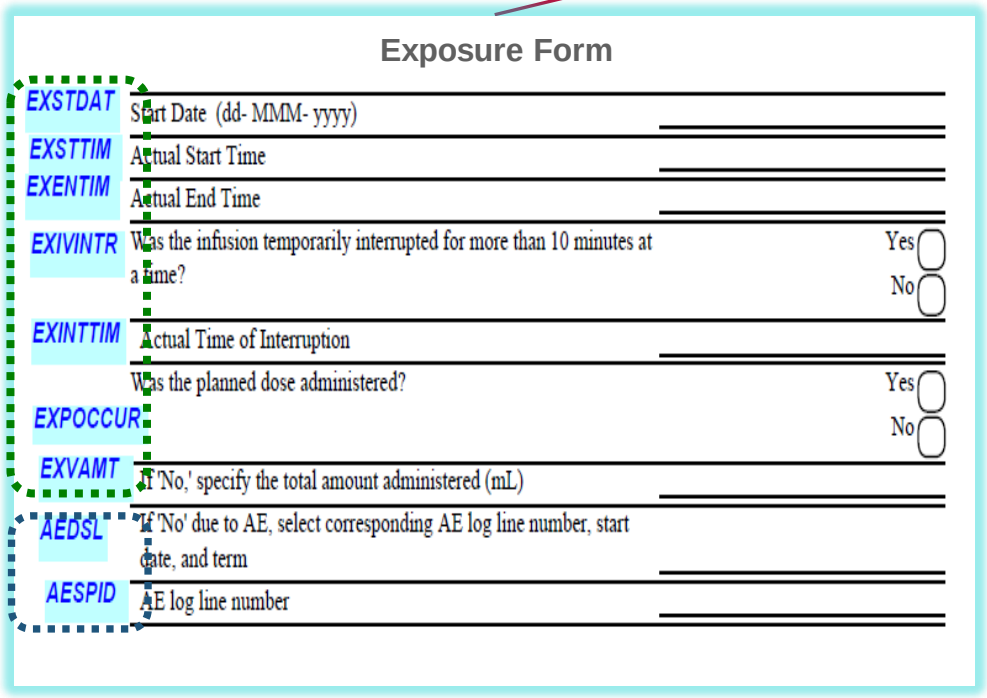
Option 2

- 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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