CDISC Implementation Committee

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Agenda

- NCI Requirement
- NCI CDISC Harmonization WG Activities
- CTSU Standard Forms ALS
- COVID-19 Form
- LPO Status Updates
- Appendix

NCI Requirement

- All CTEP IND studies activated on/after 3/1/2020 shall be CDISC compliant (submit to FDA in SDTM format)
- Studies activated prior to 2/29/20 do NOT need to be CDASH compliant but-LPOs are encouraged to launch CDASH compliant studies prior to the March 1st deadline, if possible.
  - Waivers will only be considered by the NCI for truly extenuating circumstances that meet both of the following criteria:
    - *The justification is for something beyond LPO control*
    - *The activation date was anticipated to be prior to 1/1/20*

CDISC Harmonization WG Activities

- Status Update
  - Ongoing review/ discussion – *NO CHANGE*
    - Off Treatment Code List
    - Primary Cause of Death Code List
    - Comments are under NCI review, followup is pending
  - Fragments List Reviewed/Updated as needed
  - Management of ad hoc LPO questions/ feedback as needed
  - Completed NCI Standard Forms
    - RECIST – *Verifying form details based on LPO feedback*
    - iRECIST– *NO CHANGE*
  - Finalizing the following forms – *NO CHANGE*
    - Screening
    - Off Treatment
    - Off Study

CDISC Harmonization WG Activities

- Upcoming Discussion Item: **Microbiology (MB)** &**Laboratory (LB)**

  CDISC teams have written an updated guideline for use of the ***Microbiology (MB)*** *domain vs the* ***Laboratory (LB)*** *domain*

  - Released for public review
  - Oncology Terminology also released for review
  - Circulate to CDISC Harmonization WG to gain feedback
  - Discuss on April 8th Harmonization WG call

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

COVID-19 Form

- Alliance and SWOG have developed a COVID-19 Form
  - Discussion to see if this would be helpful to potentially standardize across the LPOs
    - If a standard is developed, we would take into consideration potential need of specific forms for individual studies vs across studies.

- *LPO Feedback*
  - *tbd*

M

<INSERT COOPERATIVE GROUP or FUNDING SOURCE HERE>

Protocol Number: PROT#

ruptions and Testing

Patient ID: _____

Institution (Inst. Number): _____

form out when the first participant delay or missed visit occurs, for COVID-19 testing, or the participant protocol treatment or entire study.

TERRUPTIONS

ny delayed or missed protocol visits, labs, or assessments for any reason related to COVID-19 (diagnosis, ant or physician decision, etc)? *(check one)* ☐Yes ☐No

f these missed encounters, labs, or assessments must be reported on the *Deviations* form, per protocol

results of all COVID-19 testing.

l for COVID-19? *(check one)* ☐Yes ☐No

Result *(check one)*	*(If positive),* **Outcome**	*(If positive),* **Treatments Administered**	**Comments**
☐Positive ☐Negative ☐Indeterminate ☐Unknown	☐Recovered or Resolved ☐Recovered or Resolved with Sequelae ☐Fatal ☐Unknown		

)

THDRAWALS

aw from protocol treatment for any reason related to COVID-19 (diagnosis, travel restrictions, participant or *(check one)* ☐Yes ☐No

son for Withdrawing from Treatment (check one)
☐Diagnosis of COVID-19
☐Travel Restrictions
☐Participant Decision
☐Physician Decision
☐Other

y _____

aw from the study for any reason related to COVID-19 (diagnosis, travel restrictions, participant or physician e) ☐Yes ☐No

son for Withdrawing from Study (check one)
☐Diagnosis of COVID-19
☐Travel Restrictions
☐Participant Decision
☐Physician Decision
☐Other

y _____

atment and/or Withdraw Consent forms must be entered if the participant has withdrawn due to any reason

SWOG

COVID-19 PROTOCOL DEVIATIONS (DRAFT)

Participant Identifier ☐☐☐☐☐☐ **Study Identifier** S☐☐☐

Participant Initials _____ (L, F M)

Page: COVID-19 Protocol Deviations

Instructions: Please complete this form for all protocol deviations with the same start date. Add more loglines in R complete the CIRB and local IRB notification questions. Date is in **DD MON YYYY** format.

Were there any protocol deviations?

If yes, what is the category of the protocol deviation?

If yes, what is the start date of the deviation?

Protocol Deviation Subcategory	**Protocol Deviation***	Was CIRB notified?	If yes, date	Was the local IRB notified?
○ Major ○ Minor	_____	○ Yes ○ No	☐☐ ☐☐☐ ☐☐☐☐	○ Yes ○ No
○ Major ○ Minor	_____	○ Yes ○ No	☐☐ ☐☐☐ ☐☐☐☐	○ Yes ○ No
○ Major ○ Minor	_____	○ Yes ○ No	☐☐ ☐☐☐ ☐☐☐☐	○ Yes ○ No
○ Major ○ Minor	_____	○ Yes ○ No	☐☐ ☐☐☐ ☐☐☐☐	○ Yes ○ No

***Protocol Deviations**

Missed Study Visit
Phone or Virtual Visit
Late or Missed Study Lab
Cycle treatment Given Early or Late
Late or Missed Imaging Procedure
Late or Missed Other Study Procedure
Late or Mi
Late or Mi
Other

LPO Status Updates- *Theradex*

Current Update 03/25/2020	• Working on 8 studies in development. 1 will go to production on Friday. 10 studies that CIRB approved and 8 are in development.	
Current Issues/ Considerations	• No issues	
Prior Update 02/26/2020	• *Seed study is ready, final testing of AERS integration. Verifying the integration before initiating study builds* • *16 study builds pending* • *Pushing studies into production prior to activation, trying to avoid study rebuilds for CDISC; 5 pushed in February, only 2 activated; PIO is aware, if mods are needed, Theradex will manage updates* • *ISSUE: 1 study may need to be considered for a waiver due to a drug supply issue*	
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*
# 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 03/25/2020	• 1 study that was ready, were not allowed to activate during COVID-19 situation. Will activate study today. Have 4 more that are being built and will activate in the next couple months. 4 more in the pipeline	
Current Issues/ Considerations	• Resolved most integration issues, do not have a production version of the Central Study that goes with the CDASH AE Form.	
Prior Update 02/26/2020	• *1 study is planned for March activation* • *ISSUES: Experiencing CTEP AERS integration challenges, identified during testing; Currently working with CTSU regarding the integration items; Requested information sharing to be implemented to assist LPOs regarding challenges/issues/resolutions identified by LPOs during integration testing activities; could be helpful to SWOG & other LPOs (e.g., awareness, similar experiences, etc.)* - *CTSU will communicate challenges/issues/resolutions details and post to the Collaboration Portal*	
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*
# 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 03/25/2020	• 1st CDISC study has a date of 4/10 for activation. 3 other CDISC studies in active development and 4-5 in pipeline	
Current Issues/ Considerations	• No issues, will be getting into the AE testing to make sure we have most updated versions of Central Studies.	
Prior Update 02/26/2020	• *EA8185 – seed study scheduled for April, currently testing the integration* • *5191 – scheduled for late May activation* • *5182 – scheduled for mid July activation* • *ISSUES: 2 possible studies may need waivers, asked for waiver process information. Agreed with SWOG's request for information sharing (challenges/issues/resolutions identified by LPOs during integration testing activities), such information would be helpful.*	
Seed Study	*Identified Y/N: Yes*	*Date Completed: ~April 2020 (EA8158)*
Rave Study Build	*Initiated Y/N: Yes*	*Date Initiated: ~09/01/2019*
# 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 03/25/2020	• 1st CDASH study got an extension as it is not NCI approved. Issue with integration. 2 additional studies that are in active study build and several more in specification and development	
Current Issues/ Considerations	• Ran into a bug into CTEP AERS integration without being able to change recommendation to change on Late AE Form. Working with CTSU to get that fix. CTSU has identified a solution and will work with Alliance. All updates will be pushed to LPO URLs.	
Prior Update 02/26/2020	• *Completed GLIB forms* • *1st study is built (A081801 or A071702)* • *No waivers needed* • *ISSUES: Experiencing some integration challenges, working with CTSU*	
Seed Study	*Identified Y/N: Yes*	*Date Completed: 1/1/2020 (Alliance Global Library)*
Rave Study Build	*Initiated Y/N: TBD*	*Date Initiated: TBD*
# 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 03/25/2020	• Working through first 3 trials. All in progress but may be delays, working through mocks to align with CDISC and will start building in April. Built all the layouts in our GLIB, working on dictionaries now to handle any new dictionary values. Been a lot of work/processes that needed to be added. Flagging issues as we review the dictionaries. 275 forms have been built.	
Current Issues/ Considerations	• No issues	
Prior Update 02/26/2020	• *Completed internal GLIB review* • *Started Rave builds (~60 forms)* • *Reviewing internal dictionaries versus CDISC CT; will makes updates as needed* • *ISSUES: {None communicated at this time}*	
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)*
# 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 03/25/2020	• Have 1 study active, 3 in development.	
Current Issues/ Considerations	• None	
Prior Update 02/26/2020	• *First study has been built* • *Second study (BN006) has been built but not yet approved* • *4 additional studies planned for production in Q2 2020* • *ISSUES: {None communicated at this time}*	
Seed Study	*Identified Y/N: Yes*	*Date Completed: TBD*
Rave Study Build	*Initiated Y/N: Yes*	*Date Initiated: ~March 2019*
# 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 03/25/2020	• Working on 1 study to make CDASH compliant. Reviewing with builders and identifying variables.	
Current Issues/ Considerations	• None	
Prior Update 02/26/2020	• *TBD- not present for February Committee Meeting* • *(Dec 2019 update) Started bi-weekly meetings with Westat; Working on CRFs*	
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: {TBD- not present for February Committee Meeting}* • *01/22/2020 update: No studies planned for Q1*	

LPO Status Updates- *PBTC*

Current Update 03/25/2020	• Have a study working on for Feb 2021, 2 other studies that are in very early stages	
Current Issues/ Considerations	• No issues, Training was rescheduled due to COVID-19.	
Prior Update 02/26/2020	• *No IND studies planned in near future* • *CDISC workshop scheduled for March; planning to build CDISC-harmonized studies post workshop (all studies, including non-CTEP IND studies)* • *Reviewed ALS v7.0* • *No study builds initiated yet* • *ISSUES: {None communicated at this time}*	
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: TBD*	

LPO Status Updates- *AMC*

Current Update 03/25/2020	• In the process of reviewing the forms for an non CTEP IND study. Met with CTSU team on how to set up the forms and use the ALS. Call scheduled next week to work through roadblocks on process to implement forms that use terms that are not found in CDASH. Almost finished Rave training.	
Current Issues/ Considerations	• Trying to figure out which forms fit where. Disease specific vs the CTSU Standard Forms vs NCI Standard Forms and how to handle those moving forward.	
Prior Update 02/26/2020	• *1st targeted protocol will be AMC107, still working through the details* • *Training/ planning activities ongoing (includes Medidata Rave training & CDE review)* • *ISSUES: Communicated they need the Central Study v7.0 uploaded to their Rave url (CTSU is planning to manage this as part of ongoing onboarding activities for AMC)*	
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*

Next Steps

- Next Meeting is April 22nd 2020, from 2-3pm

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- *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

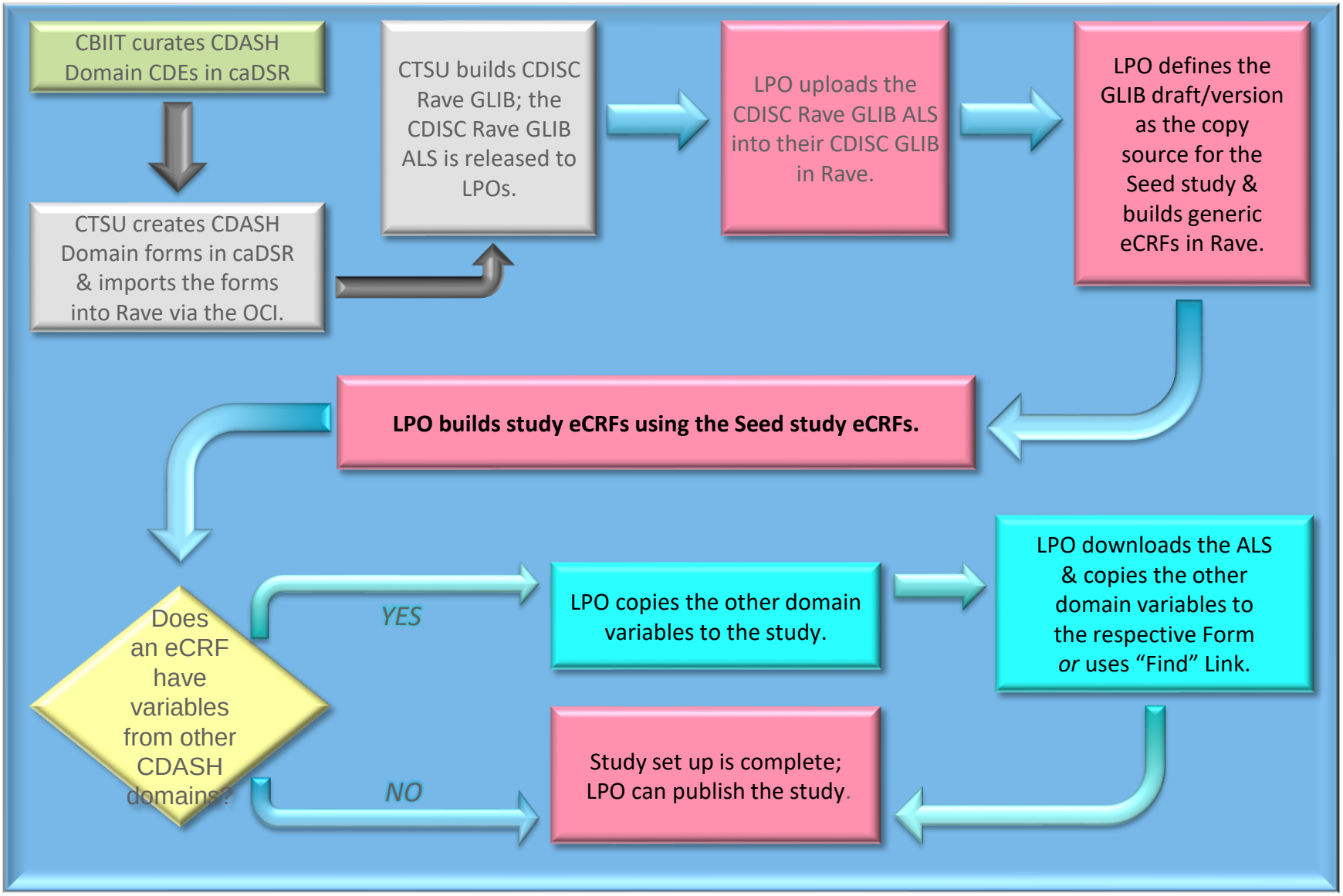
This example shows records for a trial that had two versions of inclusion/exclusion criteria.
Rows 1-3 show the two inclusion criteria and one exclusion criterion for version 1 of the protocol.
Rows 4-6 show the inclusion/exclusion criteria for version 2.2 of the protocol, which changed the minimum age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

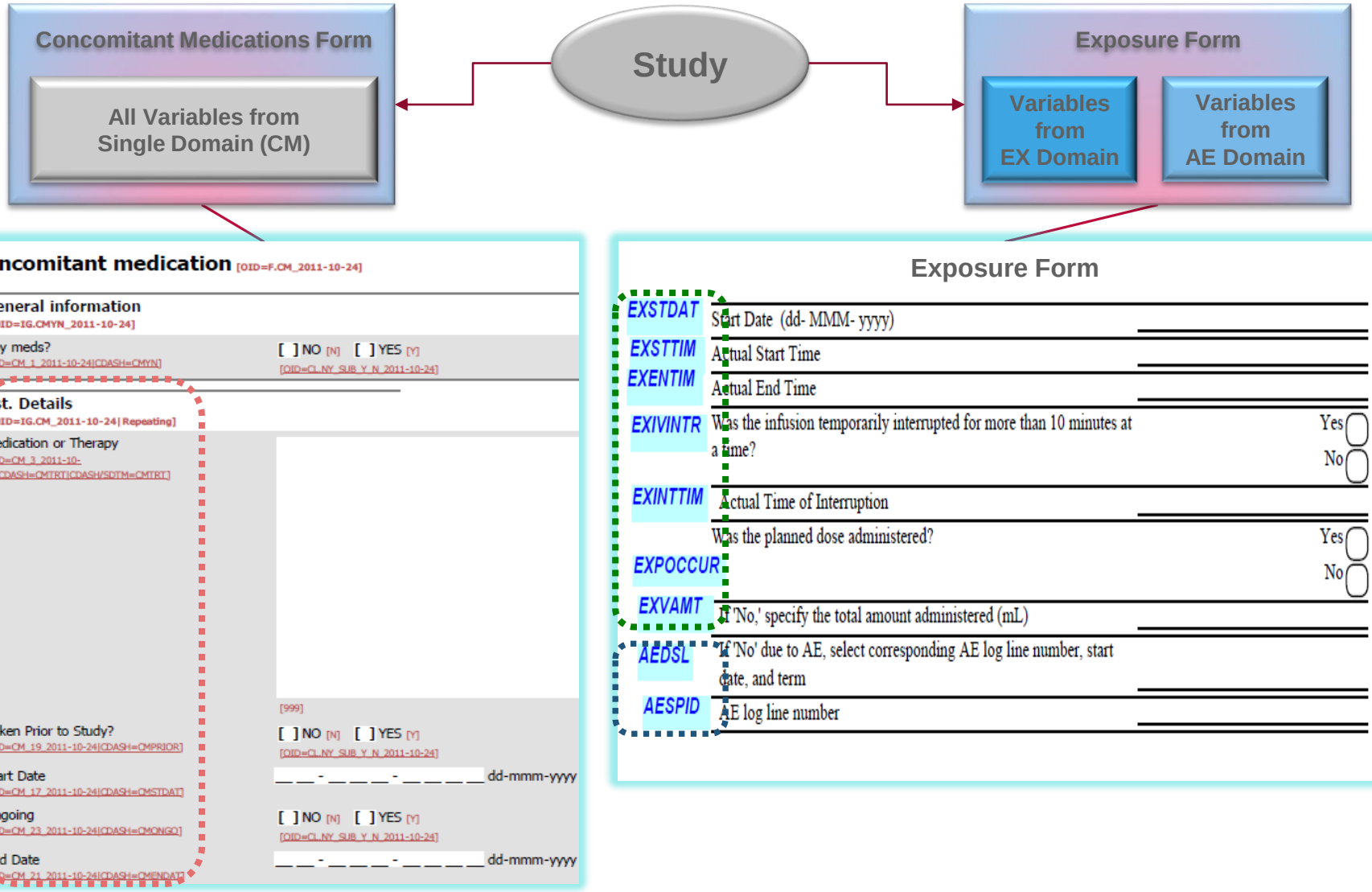
- Open the Exposure form; click add a new variable.
- Use the "Find" link on the variable definition screen to select the AE variable; click Apply to copy.

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)*

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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)*

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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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