

CDISC Implementation Committee

Neesha Desai

Agenda

- NCI Requirement
- Project Updates
- NCI CDISC Harmonization WG Update
- 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 2/28/20 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
 - AND the activation date was anticipated to be prior to 1/1/20.

NCI Requirement

- 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.

NCI CDISC Harmonization Working Group Timeline

August
2019

- Kicked off NCI CDISC Harmonization WG
- Reviewed initial content roadmap
- Prioritized content on roadmap
- Reviewed 10 ECOG-ACRIN Use Cases for CDISC Harmonization

September
2019

- Continued to review ECOG-ACRIN Use Cases and identify actions/next steps
- Addressed questions from NCI mailbox
- Began managing Fragments List
- CDISC SME presented on how to use the CDISC Oncology Domains

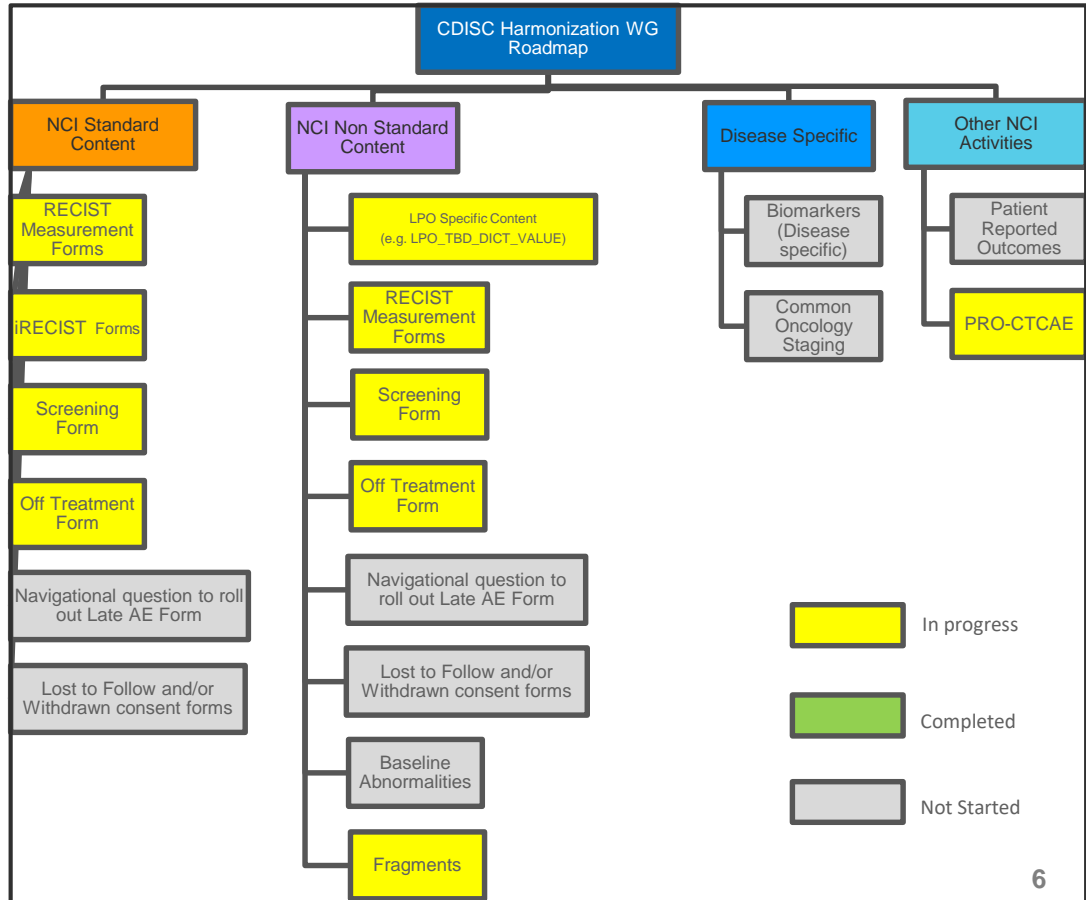
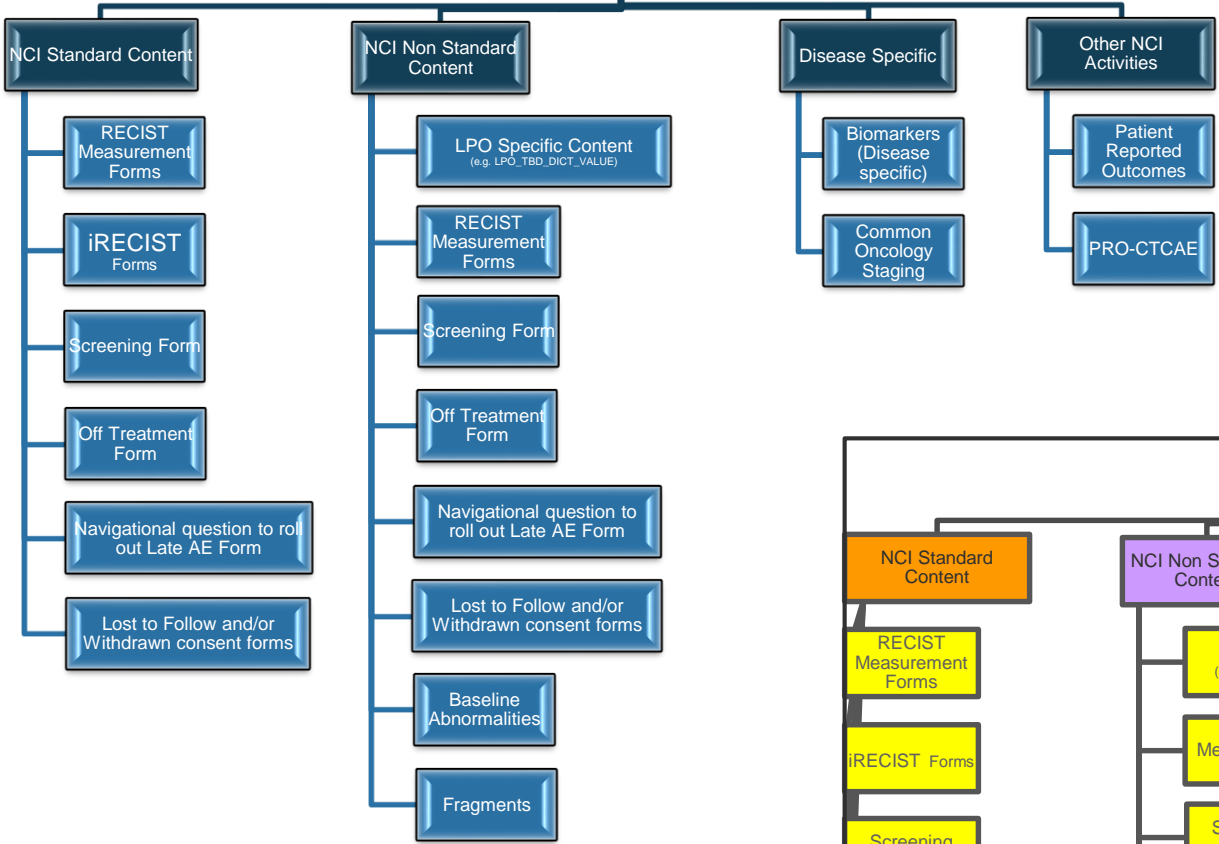
October
2019

- CDISC SME reviewed proposed approach to address RECIST and iRECIST for CDASH compliance
- Addressed questions from NCI mailbox

November
2019

- Reviewed 5 Alliance Use Cases
- Performed Gap Analysis on LPO Lost to Follow Up Standard Form, Consent Withdraw, Screening Form and Off Treatment
- Presented CDASH compliant Lost to Follow Up Standard Form, Consent Withdraw, Screening Form and Off Treatment content for review/use

CDISC Harmonization WG Roadmap



- In progress
- Completed
- Not Started

LPO Status Updates (1)

NCI/Group	Prior Update	Seed Study identified	Target date to complete Seed Study	# of CDASH/ SDTM harmonized CRFs (templates/ seed study CRFs)	Rave Study Build initiated	Target date to initiate Rave Study Build	# of CTEP IND Studies planned for Q1 2020 activation
Theradex	<p>PRIOR UPDATE: Built 40 forms in caDSR and working on pulling those into Rave. Moving ahead.</p> <p>CURRENT UPDATE: “Reviewing each of the forms and making updates as needed.</p> <p>Will you be ready by Jan 1, 2020 or do you need a deadline? Everything will be done and tested by the end of the 2nd week of December. Busy with a number of studies. Trying to bring 8-12 studies in activation before 12/31/19. Target is 8 studies that Jeff Moscow thinks we will be able to get active by 12/31. Some of those have OEWG deadlines further out. Already built them in pre-CDASH format. Won't be able to build with the new seed study until 12/13. Have not started building any new studies with CDASH structure.</p> <p>Forms have been built, once completed will work on edit checks</p>	Yes	~ 11/25/2019	<p>68 Seed Study CRFs targeted; 53 forms created and imported into Rave</p> <p>7 still have issues but are in Rave</p> <p>**All forms have been built and imported in Rave. Working on edit checks.</p>	Yes	End of Dec...be done with custom functions and validations	<p>~7 studies w/ Dec 2019 OEWG deadlines (<i>some study builds already initiated, may need to be rebuilt</i>)</p> <p>~5 studies w/ Jan 2020 OEWG deadlines</p> <p>~1 study w/ March 2020 OEWG deadline</p> <p>*5 studies active in Dec, rest will move to Jan Q1</p> <p>Any new study builds will be with CDASH seed study</p>

LPO Status Updates (1)

NCI/Group	Prior Update	Seed Study identified	Target date to complete Seed Study	# of CDASH/ SDTM harmonized CRFs (templates/ seed study CRFs)	Rave Study Build initiated	Target date to initiate Rave Study Build	# of CTEP IND Studies planned for Q1 2020 activation
SWOG	<p>PRIOR UPDATE: Started first study build, all forms created as PDFs and doing an SDTM mapping and controlled term. Not in Rave yet, but working on database structure.</p> <p>CURRENT UPDATE: Rave study build not started close to finalizing mock ups</p> <p>Will you be ready by Jan 1, 2020 or do you need a deadline? If anything was close to that deadline, SWOG will be okay making that deadline, prioritized their studies to meet the deadline. Would have been nice to know there could have been a buffer, so we delayed them.</p>	Yes	~ 01/xx/2020	<i>28 forms fully mapped to SDTM and built in Rave and have been 28 left</i>	Yes	<p>~ 11/01/2019 (to be verified)</p> <p><i>Should have the first study built in Rave in a few weeks and then working on edit checks</i></p>	<p><i>2 studies may activate Feb</i></p> <p><i>Few in March</i></p> <p><i>4 to activate March 118,1929,1933, 1925 (March or April)</i></p>

LPO Status Updates (2)

NCI/Group	Prior Update	Seed Study identified	Target date to complete Seed Study	# of CDASH/ SDTM harmonized CRFs (templates/ seed study CRFs)	Rave Study Build initiated	Target date to initiate Rave Study Build	# of CTEP IND Studies planned for Q1 2020 activation
<p>ECOG-ACRIN</p>	<p>PRIOR UPDATE: 10 standard forms into seed study.</p> <p>CURRENT UPDATE: no concerns reported at this time.</p> <p>Will you be ready by Jan 1, 2020 or do you need a deadline? 3 studies for the extension of deadline. Were ready to with Rave before the deadline, due to circumstances due to ECOG-ACRIN's control, date was pushed to Feb. EAA171.</p> <p>EA5191 – Rebuild of 5152, doing a database architect copy, needs to be ready by 5/23. Were going to submit a request to keep the data tables the same</p> <p>EA2187 – OEWG date of 1/31 – Not sure if that will activate before then. Not CDISC compliant, built this before the ALS.</p>	<p>Yes</p>	<p>To be verified</p>	<p>All forms have been identified for harmonization, # to be confirmed.</p>	<p>Yes (<i>in sandbox</i>)</p>	<p>~ 09/01/2019</p>	<p>~ 4 studies</p>

LPO Status Updates (2)

NCI/Group	Prior Update	Seed Study identified	Target date to complete Seed Study	# of CDASH/ SDTM harmonized CRFs (templates/ seed study CRFs)	Rave Study Build initiated	Target date to initiate Rave Study Build	# of CTEP IND Studies planned for Q1 2020 activation
Alliance	<p>PRIOR UPDATE: Taking existing standard forms and seed study and comparing them with both ALS files. Some building has been started, moving forward and making progress.</p> <p>CURRENT UPDATE:</p> <p>Will you be ready by Jan 1, 2020 or do you need a deadline?</p> <p>2 studies are ready for activations but OEWG keeps extending deadline</p> <p>1 study had an OEWG study of 1/20, preparing it to activate on time.</p> <p>Rebuilding seems to be a lot of rework.</p>	<p>Alliance Global Library</p> <p>First actual study identified</p>	1/1/2020 for Global Library	<p>39 forms fully harmonized with CDASH with unit test completed</p> <p>15 have been built in Rave, but only touched on edit checks, just started on custom functions.</p>	TBD	TBD	<p>March and one in April,</p> <p>Confident to reach deadlines</p> <p>Looking to see if there will be a third study, potential activations January...internal discussions</p>

LPO Status Updates (3)

NCI/Group	Prior Update	Seed Study identified	Target date to complete Seed Study	# of CDASH/ SDTM harmonized CRFs (templates/ seed study CRFs)	Rave Study Build initiated	Target date to initiate Rave Study Build	# of CTEP IND Studies planned for Q1 2020 activation
CCTG	<p>PRIOR UPDATE: Continued to work on the CCTG global library of mock forms and working to make that CDISC compliant...starting preliminary work to map to SDTM, moving forward with building seed study.</p> <p>CURRENT UPDATE: Finalizing internal review on CRFs. Submitting a few calls in next couple weeks and training to go over questions.</p> <p>Will you be ready by Jan 1, 2020 or do you need a deadline? Would like an extension for additional work</p>	Building Global Library first	TBD	Working through Global Library and mock templates	Not yet		<p><i>No studies identified at this point. Main concern is not the Rave build, more the SDTM and items touched by our SAS programs.</i></p> <p><i>Identified 3 studies</i></p> <ol style="list-style-type: none"> <i>1. May 2020 (MA40)</i> <i>2. Q3 of 2020 (2 studies)</i>

LPO Status Updates (3)

NCI/Group	Prior Update	Seed Study identified	Target date to complete Seed Study	# of CDASH/ SDTM harmonized CRFs (templates/ seed study CRFs)	Rave Study Build initiated	Target date to initiate Rave Study Build	# of CTEP IND Studies planned for Q1 2020 activation
NRG	<p>PRIOR UPDATE: Held a lessons learned meeting, working on a path forward.</p> <p>CURRENT UPDATE: Seed study has been built in Rave, planning to send ALS for review to verify. Working on 2nd Rave study build. Current concerns include trying to overcome historic processes for data collections in meeting CDISC reporting requirements and determining the optimal ways to collect the different types of data and streamline organizational processes/ impact.</p> <p>Will you be ready by Jan 1, 2020 or do you need a deadline? Does not need an extension</p>	Yes		Every external form (~50) has been harmonized; internal forms are pending	Yes	~ March 2019	<p>TBD (<i>update will be provided offline</i>)</p> <p><i>NRGY020 – Feb activation – will implement the CTSU AE forms</i></p> <p><i>BN006 – Activate mid January</i></p>

LPO Status Updates (4)

NCI/Group	Update	Seed Study identified	Target date to complete Seed Study	# of CDASH/ SDTM harmonized CRFs (templates/ seed study CRFs)	Rave Study Build initiated	Target date to initiate Rave Study Build	# of CTEP IND Studies planned for Q1 2020 activation
COG	<p>PRIOR UPDATE: 13 forms and looking through forms to identify which are 1 to 1 mapping, forward mapping and backwards mapping to see if any require CDASH domains and variables to questions. Have not started study build at this time.</p> <p>CURRENT UPDATE: Started bi-weekly meetings with Westat. Working on CRFs</p> <p>Will you be ready by Jan 1, 2020 or do you need a deadline? Need a waiver, not ready to activate</p>	Not yet	TBD	TBD	Not yet	TBD	No studies planned for Q1

Next Steps

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

Appendix

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

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.

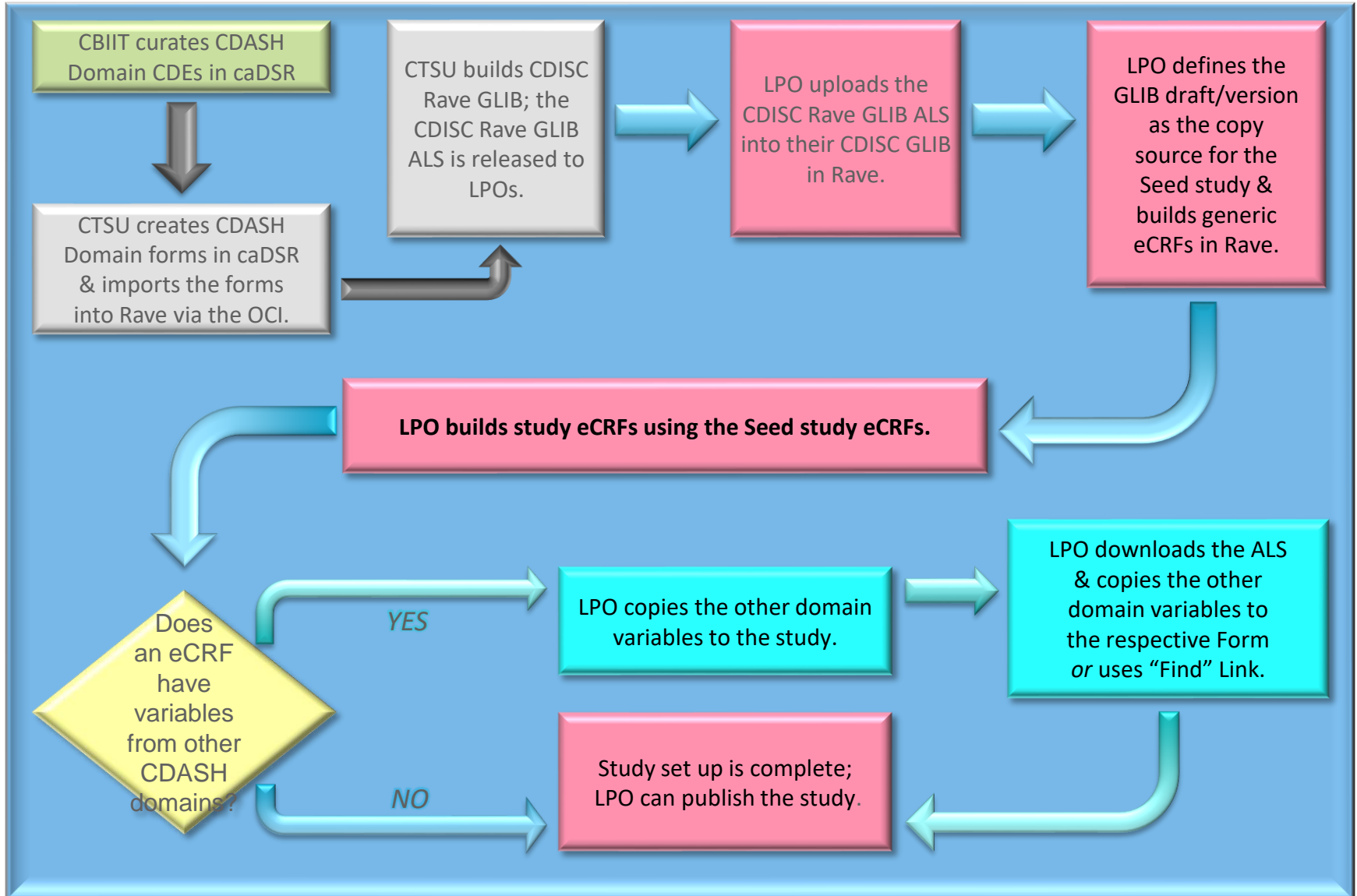
Rows 4-6 show the inclusion/exclusion criteria for version 2.2 of the protocol, which changed the minimum age entry from 21 to 18.

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 <i>(e.g., DEMOGRAPHICS)</i>	CDASH Domain Name <i>(e.g., DEMOGRAPHICS)</i>	<no change: same as caDSR>
Form OID	caDSR Form Long Name <i>(e.g., DEMOGRAPHICS)</i>	2 letter CDASH Domain Name <i>(e.g., DM)</i>	Update by CTSU
Variable OID	Short Name of the CDE <i>(e.g., RACE)</i>	CDASH/SDTM Variable Name <i>(e.g., RACE)</i>	<no change: same as caDSR>
Field Name	caDSR CDE Long Name + PID + MajorV + MinorV <i>(e.g., Race PID6343384_V1_0)</i>	Variable Label + PID + MajorV + MinorV <i>(e.g., Race PID6343384_V1_0)</i>	<no change: same as caDSR>
Field OID	2 letter domain prefix + CDASH/ SDTM variable <i>(e.g., RACE)</i>	2 letter domain prefix + CDASH/SDTM Variable Name <i>(e.g., RACE)</i>	<no change: same as caDSR>
Field Label	Question Text <i>(e.g., Which of the following five racial designations best describes you? (More than one choice is acceptable.))</i>	Question Text or Variable label <i>(e.g., Which of the following five racial designations best describes you? (More than one choice is acceptable.))</i>	Update by CTSU **Specify the Variable label for Field Labels without question text **
Data Dictionary Name	caDSR Value Domain Long Name + PID + MajorV <i>(e.g., CDISC_SDTM_RACE_PID6343345_V1_0F)</i>	caDSR Value Domain Long Name + PID + MajorV	<no change: same as caDSR>
Data Dictionary Values-User Data String	Permissible Value Meaning (PVM) <i>(e.g., Native Hawaiian or Other Pacific Islander)</i>	NCI preferred term <i>(e.g., Native Hawaiian or Other Pacific Islander)</i>	<no change: same as caDSR>
Data Dictionary Values-Coded Data String	Permissible Value (PV) <i>(e.g., NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER)</i>	Submission Value <i>(e.g., NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER)</i>	<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 <i>(may be either the max length of dictionary value or extendable value;; e.g., \$100)</i>	char <i>(may be either the max length of dictionary value or extendable value; e.g., \$100)</i>	<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	<i>(e.g., DropDownList)</i>	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

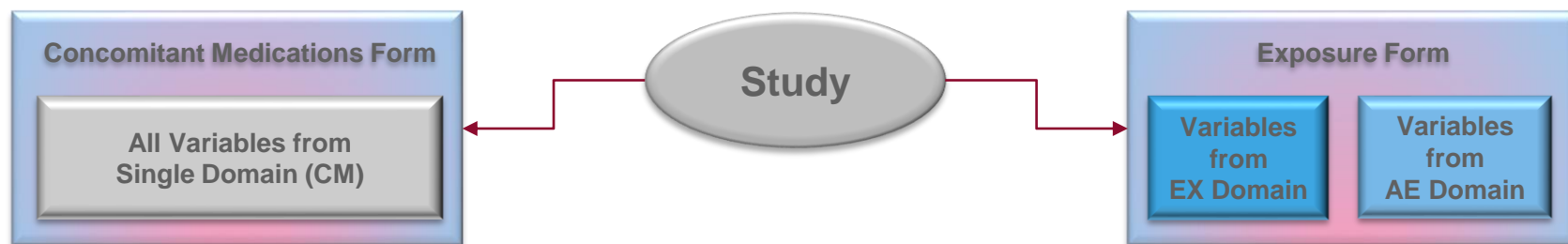
- Open the Exposure form; click add a new variable.
- Use the “**Find**” link on the variable definition screen to select the AE variable; click Apply to copy.

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)



Concomitant medication [OID=F.CM_2011-10-24]

General information
[OID=IG.CMYN_2011-10-24]

Any meds? NO [N] YES [Y]
[OID=CM_1_2011-10-24|CDASH=CMYN] [OID=CL.NY.SUB.Y.N_2011-10-24]

1st. Details
[OID=IG.CM_2011-10-24|Repeating]

Medication or Therapy
[OID=CM_3_2011-10-24|CDASH=CMTRT|CDASH/SDTM=CMTRT]

[999]

Taken Prior to Study? NO [N] YES [Y]
[OID=CM_19_2011-10-24|CDASH=CMPRIOR] [OID=CL.NY.SUB.Y.N_2011-10-24]

Start Date _____ dd-mmm-yyyy
[OID=CM_17_2011-10-24|CDASH=CMSTDAT]

Ongoing NO [N] YES [Y]
[OID=CM_23_2011-10-24|CDASH=CMONGO] [OID=CL.NY.SUB.Y.N_2011-10-24]

End Date _____ dd-mmm-yyyy
[OID=CM_21_2011-10-24|CDASH=CMENDAT]

Exposure Form

EXSTDAT Start Date (dd- MMM- yyyy) _____

EXSTTIM Actual Start Time _____

EXENTIM Actual End Time _____

EXIVINTR Was the infusion temporarily interrupted for more than 10 minutes at a time? Yes No

EXINTTIM Actual Time of Interruption _____

Was the planned dose administered? Yes No

EXPOCCUR _____

EXVAMT If 'No,' specify the total amount administered (mL) _____

AEDSL If 'No' due to AE, select corresponding AE log line number, start date, and term _____

AESPID AE log line number _____

LPO Impact Analysis: Beta Release GLIB (1)

#	Document	LPO Findings/ Recommendations/ Questions	Decision
1	GLIB ALS	<p>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</p> <p>With the final release in July, will the GLIB and other ALS files be updated using the newest CDASH and SDTM controlled terminology packages?</p>	<p>CTSUS will do an impact analysis (for CT Packages released by CDISC before July 2019) to understand the potential impact to our timeline.</p> <p>The intent is to provide documents as current as possible to CDISC releases/ updates; this must be done in consideration of the implementation timelines.</p>
2	GLIB Release Notes: Section 3.2 Standard Conventions – Table 6	<p>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.</p>	<p>05/02/2019 CDISC Integration FG:</p> <ul style="list-style-type: none"> • 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. <p>“Standard Forms” applies to the CTSU Standard Forms ALS, “Non-Standard Forms applies to variables not specified in the CTSU Standard Forms ALS.</p>
3	GLIB Release Notes: Section 3.2 Standard Conventions – Table 7	<p>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)</p>	<p>Maintain the same SAS label as in the CDISC GLIB for consistency across LPOs.</p>
4	GLIB ALS	<p>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?</p>	<p>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”.</p> <p>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.</p>

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.	<p>LPOs can decide to use the NCI Preferred Term or the CDISC Synonym for the User Data String in Rave.</p> <p>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.</p> <p>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.</p>
6	GLIB ALS	<p>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.</p> <p>i. Rave does not allow us to subset the dictionary choices at the field level – a separate dictionary must be created</p> <p>ii. Example: NY. Sometimes Unknown or Not Applicable are not valid responses for a question</p> <p>iii. The Alliance would be open to a standard naming convention in this situation.</p>	<p>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.</p> <p>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.</p> <p>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.</p>
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	<p>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</p> <p>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?)</p>	<p>All CTEP IND studies activated on/after 1/1/2020 must be CDISC compliant.</p> <p>CDISC Compliance is highly recommended for studies that activate prior to the 2020 date.</p> <p>The CDISC SME to provide additional feedback at the "Overview of FDA Submission Process" Webinar on May 22nd, 2019.</p>
9	NCI/CDISC Best Practices Document	<p>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.</p>	<p>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.</p>
10	NCI/CDISC Best Practices Document	<p>Does NCI/CTEP submit data to FDA on NCTN trials? If so, study by study or aggregated across studies?</p>	<p>No decision required, NCI does not submit to the FDA.</p>
11	NCI/CDISC Best Practices Document	<p>Throughout the entire document, please be specific what CDISC compliant means. CDASH, SDTM, ADaM, etc.</p> <p>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.</p>	<p>The FDA requirement is SDTM. the NCI requirement is CDASH.</p> <p>CDASH compliance makes SDTM compliance easier to achieve.</p> <p>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.</p>



**NATIONAL
CANCER
INSTITUTE**

www.cancer.gov

www.cancer.gov/espanol