

CDASH CDEs

11/28/2018

CDASH CDEs

- CDISC approved NCI Implementation of CDISC Share variables
- CBIIT will curate future SDTM CDEs (as requested by LPOs based on data submission)
- Eligibility Criteria (Supplemental Qualifiers)
 - Curated by CBIIT caDSR curation team for NRDS LPOs
 - Allows LPOs to keep their existing libraries of Eligibility Criteria questions

CDASH CDEs *continued...*

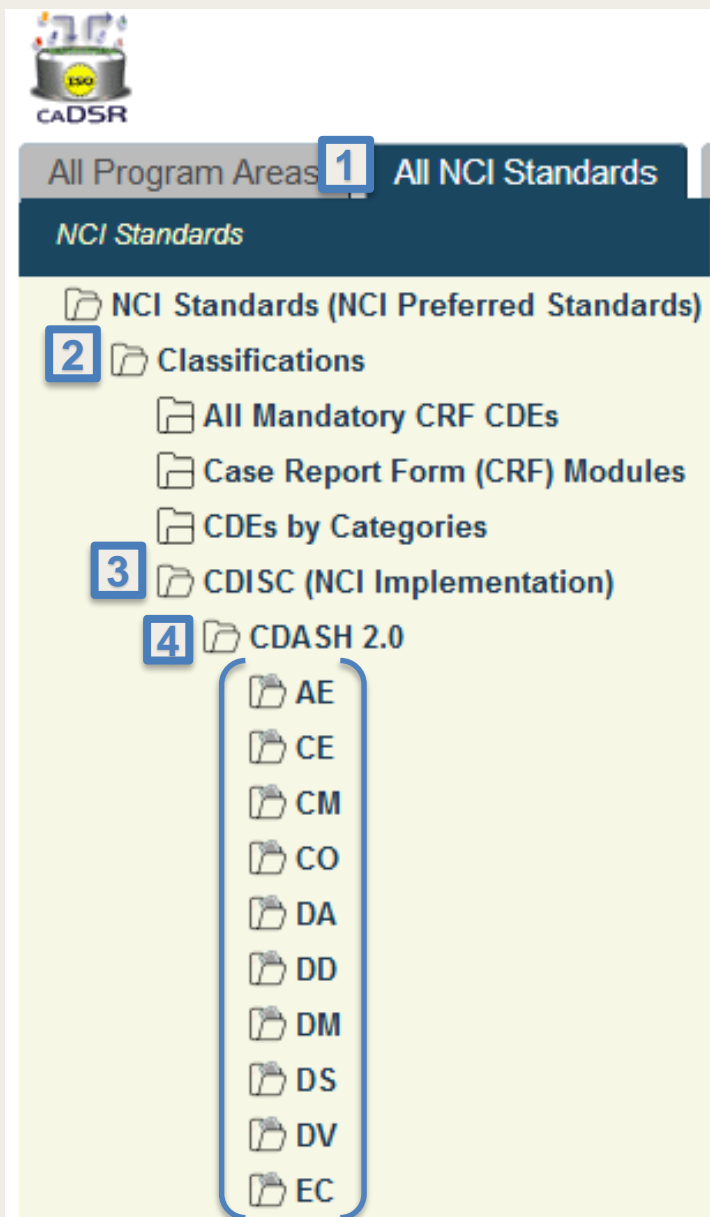
- Date datatype
 - Max length of 11 and does not specify a display format
- Max length for non-enumerated CDEs
 - Set reasonable max length based on expected response/data
 - Text based CDEs (ex., comments) 200 character limit (this also supports SAS data submissions to FDA)
- Enumerated CDEs
 - Max length based on CDASH/SDTM controlled terminology

CDASH CDEs *continued...*

In the caDSR CDE Browser:

1. Go to the '**All NCI Standards**' tab
2. Expand the '**Classifications**' folder
3. Expand the '**CDISC (NCI Implementation)**' folder
4. Expand the '**CDASH 2.0**' folder

Folders for all CDASH Domains will be displayed; click on a specific CDASH Domain to view the CDEs curated for said Domain.





**NATIONAL
CANCER
INSTITUTE**

www.cancer.gov

www.cancer.gov/espanol



CDISC IMPLEMENTATION

RAVE GLOBAL LIBRARY

CDISC Rave Global Library: CTSU Process Overview

1. CDASH Domain forms are built in the caDSR FormBuilder.
2. CDASH Domain forms are imported from the caDSR into Rave via the OCI.
3. Rave Study Build activities are managed.
4. CDISC Rave Global Library (GLIB) ALS is created.
5. Compliance review is managed for the CDISC Rave GLIB ALS.
6. Finalized CDISC Rave GLIB ALS is provided to LPOs.

CDISC Rave Global Library: CTSU Change Matrix (1)

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_VI_0)	Variable Label + PID + MajorV + MinorV (e.g., Race PID6343384_VI_0)	<no change: same as caDSR>
Field OID	CDASH variable (e.g., RACE)	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**

CDISC Rave Global Library: CTSU Change Matrix (2)

Rave Attribute	caDSR/ OCI Attribute	CTSU CDISC Global library	Change Management
Data Dictionary Name	Defined by CBIT (e.g., <i>CDISC_SDTM_RACE_PID6343345_VI_OF</i>)	CDISC Codelist Submission value	Update by CTSU **Specify the dictionary name as per CDISC submission value**
Data Dictionary Values- User Data String	Permissible Value Meaning (PVM) (e.g., <i>Native Hawaiian or Other Pacific Islander</i>)	NCI preferred term (e.g., <i>Native Hawaiian or Other Pacific Islander</i>)	<no change: same as caDSR>
Data Dictionary Values- Coded Data String	Permissible Value (PV) (e.g., <i>NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER</i>)	Submission Value (e.g., <i>NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER</i>)	<no change: same as caDSR>

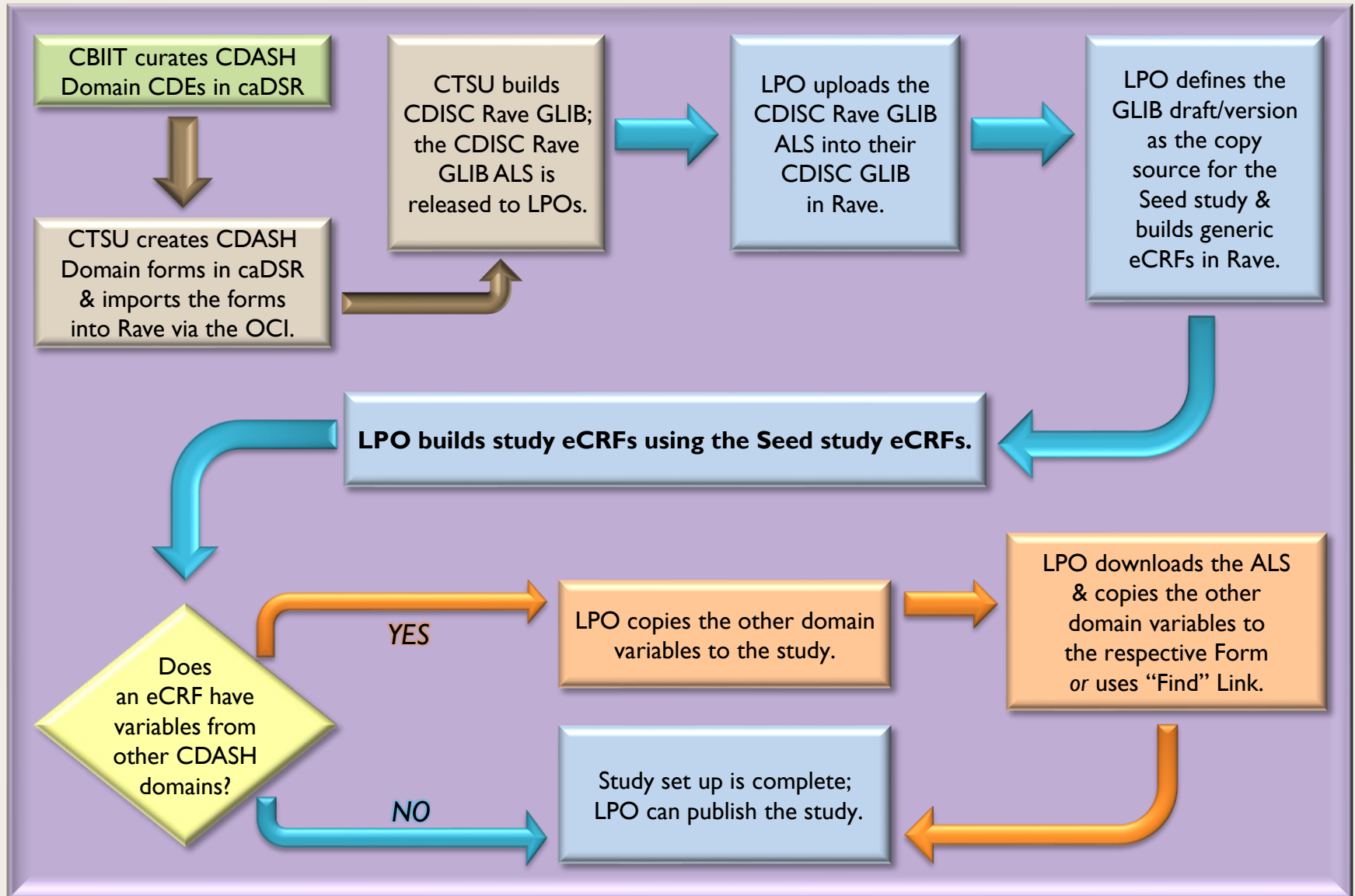
CDISC Rave Global Library: CTSU Change Matrix (3)

Rave Attribute	caDSR/ OCI Attribute	CTSU CDISC Global library	Change Management
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>

CDISC Rave Global Library: CTSU Change Matrix (4)

Rave Attribute	caDSR/ OCI Attribute	CTSU CDISC Global library	Change Management
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**

CDISC Implementation Workflow




Considerations

- Data Transformation by LPOs
 - Rave study data will have to be transformed during the SDTM file generation by SAS programs.
- CDISC SHARE Version Management
 - Post initial implementation, new versions of CDISC SHARE will be managed at the CDISC GLIB level (CTSU) and the Seed study eCRF level (LPOs).
- EC Forms & Supplemental Questions
 - Discussions are ongoing regarding best management of EC Supplemental Questions with minimized impact to LPOs; process changes will be communicated.
 - At this time LPOs should maintain the current process flow for managing ECs across OPEN and Rave.

Considerations: EC Forms

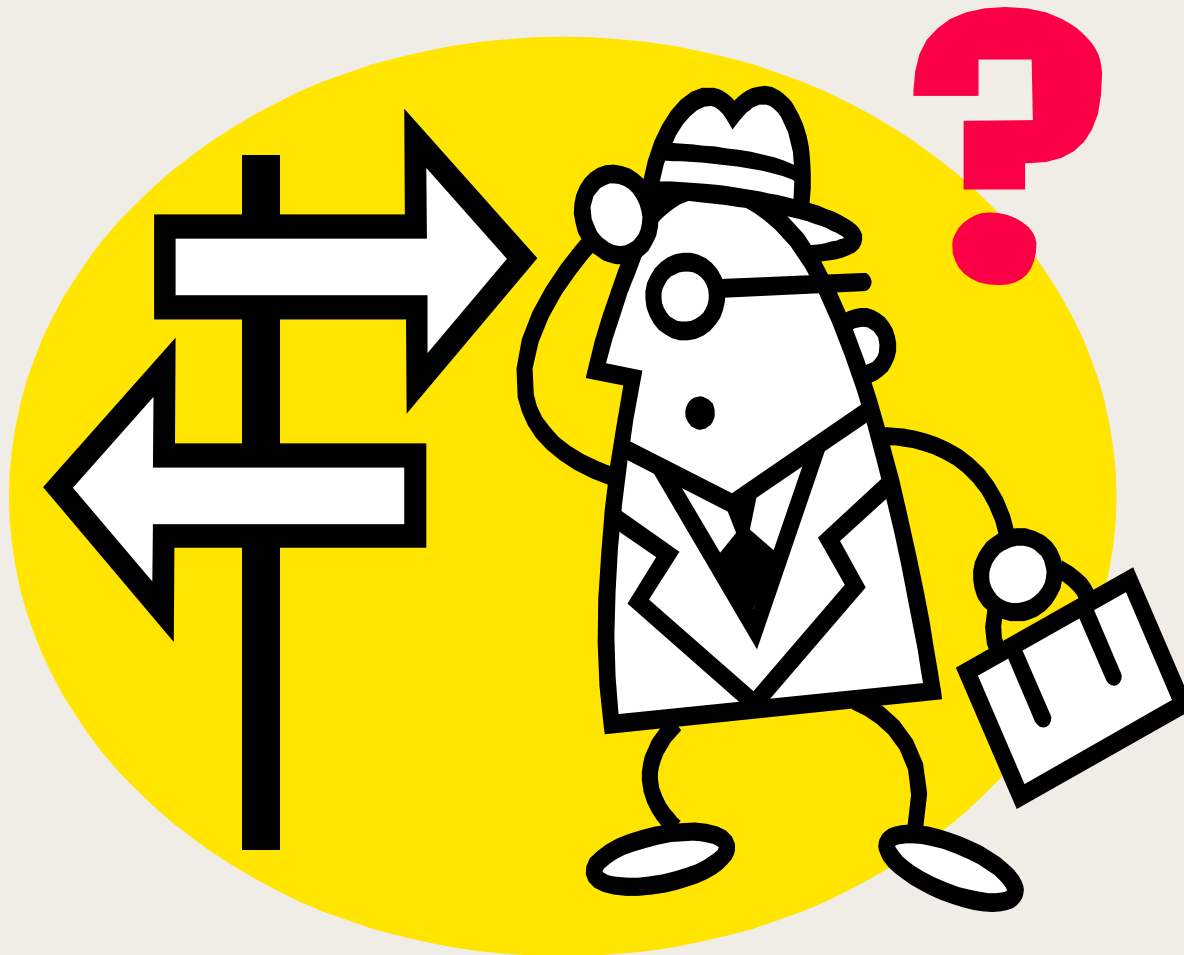
- Current processes for LPOs & EC Forms across OPEN & Rave
 - Use/ reuse existing CDEs during caDSR Formbuilding activities.
 - Curate new CDEs in the caDSR as needed.
 - Build EC forms in the caDSR.
 - Import EC forms into Rave using the OCI.
- EC Forms & Supplemental Question Considerations
 - As part of the CDISC implementation, EC Forms & all questions will have to be CDISC compliant.
 - Max length and 'Date' data type will have to be specified during caDSR curation activities for all EC CDEs.
 - Q: LPO preference for curation?

Short Term and High Level Timelines



Milestone	Estimated Date	Responsibility
Identify and finalize the CDISC SHARE files to be used for the Rave GLIB	Jul 2018	CTSU
Build Rave GLIB using CDISC SHARE (beta release)	Oct/Nov 2018	CTSU
Beta Release CDISC-compliant OPEN ALS v7.0	Dec 2018	CTSU
Beta Release CDISC-compliant Rave-CTEP-AERS Integration ALS v4.0	Feb 2019	CTSU
Start piloting with one NCTN	Apr 2019	LPO, CTSU
Release final fully compliant standard forms and CDISC SHARE based ALS	Jul 2019	LPO

Questions?





APPENDIX: eCRF BUILD SCENARIOS

eCRFs Build Scenarios

- Rave eCRFs may have different build scenarios.
 - Variables from a single domain.
 - Variables from multiple domains.
 - Custom variables that do not map to CDASH/SDTM.

eCRFs Build Scenarios: Single Domain

- All variables in the 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: Multiple Domains (1)

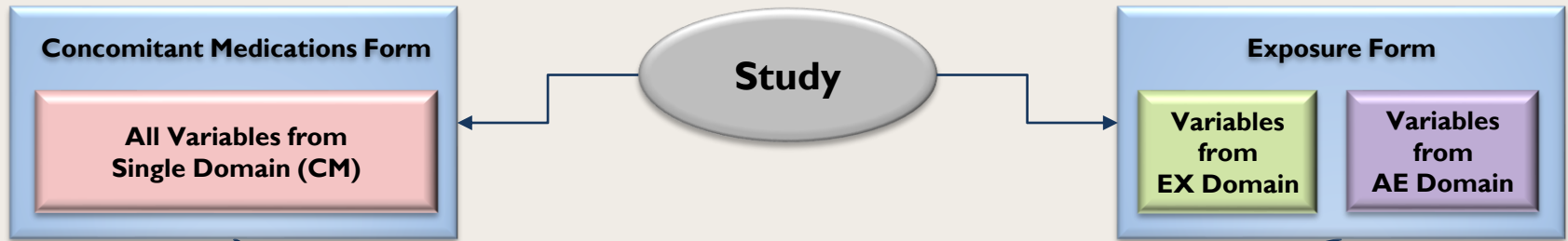
- Variables in the eCRF are from more than one domain.
Example: an Exposure form with variables from the EX and AE domains
 - Follow the steps specified in the “eCRFs Build Scenarios: Single Domain” slide to build an Exposure form with variables from the EX domain.
 - Using the copy wizard, copy the required variables from the AE domain to the study draft.

eCRFs Build Scenarios: Multiple Domains (2)

- 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 Scenario 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 _____