

CDISC Implementation Committee Meeting

NCI CBIT CDEs for EC Forms

12/19/2018

CDEs to Support Eligibility Checklists (EC)

- **EC Form Questions**
 - Can have 3 different types of CDEs
 1. CDASH Share Data Elements (already curated)
 2. Inclusion/Exclusion Criteria
 3. Supplemental Question (not already curated CDASH elements)

EC CDEs – CDASH Share Elements

- No discussion needed – use curated CDASH 2.0 CDEs

For example:

Data Element Details	
Public ID:	6380049
Version:	1.0
Long Name:	Subject Identifier for the Study
Short Name:	SUBJID
Preferred Question Text:	What is the subject identifier?
Definition:	A unique subject identifier within a site and a study.
Value Domain:	CDISC Variable Terminology Identifier
Data Element Concept:	CDISC Domain Subject Identifier
Context:	NCI Standards
Contexts using this CDE:	None
Workflow Status:	DRAFT NEW
Origin:	CDISC:Clinical Data Interchange Standards Consortium

EC CDEs – *Inclusion/Exclusion Criteria*

- CDASH does not provide a variable for individual inclusion/exclusion questions
- Suggest not curating these unless the LPOs want to use the CDASH Controlled Vocabulary standard for PVs

Value Domain Details	
Public ID:	6343337
Version:	1.0
Long Name:	CDISC SDTM Yes No Unknown or Not Applicable Response Terminology Indicator
Short Name:	NY
Context Name:	NCI Standards
Definition:	Terminology codelist used with Yes No Unknown or Not Applicable Response within the Clinical Data Interchange Standards Consortium Study Data Tabulation Model. An event, entity or condition that typically characterizes a prescribed environment or situation and determines or aids in determining whether certain stated circumstances exist or criteria are satisfied.
Workflow Status:	DRAFT NEW
Registration Status:	Qualified
Data Type:	CHARACTER
Unit of Measure:	
Display Format:	
Maximum Length:	2
Minimum Length:	
Decimal Place:	
High Value:	
Low Value:	
Value Domain Type:	Enumerated

Permissible Values			
PV	PV Meaning	PV Meaning Concept Codes	PV Meaning Description
N	No	C49487	The non-affirmative response to a question.
NA	Not Applicable	C48660	Determination of a value is not relevant in the current context.
U	Unknown	C17998	Not known, not observed, not recorded, or refused.
Y	Yes	C49488	The affirmative response to a question.

Inclusion/Exclusion Data – Submission Guidance Needed

- Direction could be provided by the CDISC Implementation Committee on how to submit the data

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

EC CDEs – Supplemental Qualifiers Domain Questions

- NCI CBIT team will curate CDEs for the LPOs requesting assistance
- Only for EC Forms where questions aren't type 1 (existing CDASH) or 2 (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

RAVE GLOBAL LIBRARY

CDISC Rave Global Library: CDASH Study Build Metrics Summary (1)

# of Forms	26	
# of unique Fields	628	
# of total Fields	755	<i>Includes 26 Form OIDs</i>
# of unique Data Dictionaries	148	
# of Custom Functions	0	

CDISC Rave Global Library: CDASH Study Build Metrics Summary (2)

CDASH Domain Form	# Fields/ Rave form	# Dictionaries/Rave form
Adverse Events (AE)	56	25
Clinical Events (CE)	34	8
Prior and Concomitant Medications (CM)	40	8
Comments (CO)	5	0
Drug Accountability (DA)	34	9
Death Details (DD)	20	3
Demographics (DM)	18	6
Disposition (DS)	15	5
Protocol Deviations (DV)	14	1
Exposure as Collected (EC)	38	17
ECG Test Results (EG)	23	8
Exposure (EX)	35	15
Findings About (FA)	31	17
Healthcare Encounters (HO)	22	4
Inclusion/Exclusion Criteria Not Met (IE)	13	2
Laboratory Test Results (LB)	27	9
Medical History (MH)	33	10
Microscopic Findings (MI)	27	11
Pharmacokinetic Concentrations (PC)	22	4
Physical Examination (PE)	25	8
Procedures (PR)	49	17
Reproductive System Findings (RP)	15	3
Subject Characteristics (SC)	22	3
Skin Response (SR)	58	25
Substance Use (SU)	20	3
Vital Signs (VS)	59	25

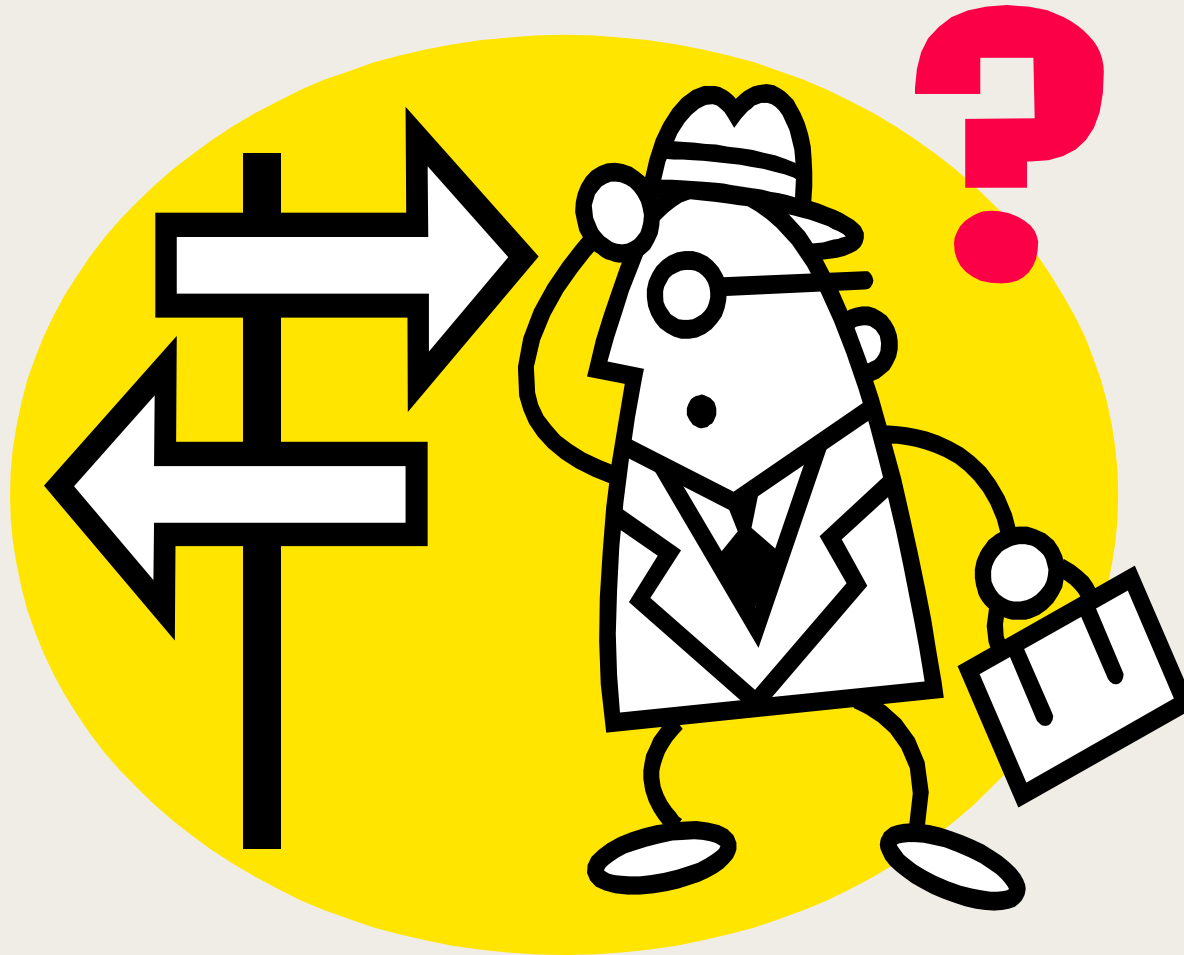
CDISC GLIB Implementation Timeline

Milestone	Date	Responsibility
Identify and finalize the CDISC SHARE files for curation activities.	Completed	CBIIT
Curate CDASH Domain in caDSR.	Completed	CBIIT
Build CDASH Domain forms in the caDSR FormBuilder.	Completed	CTSU
Import caDSR CDASH Domain Forms into Rave via the OCI.	Completed	CTSU
Build Rave GLIB.	Dec 28 th , 2018	CTSU
Update CTEP-AERS per CDISC requirements	<i>*in parallel with CTSU activities</i>	CTIS
Create CDISC Rave Global Library (GLIB) ALS.	Jan 31 st , 2019	CTSU
Perform compliance review on the CDISC Rave GLIB ALS.	Feb 22 nd , 2019	CDSIC PM
Beta Release CDISC-compliant OPEN ALS v7.0. <i>*Timeline dependent on CDISC SME Support</i>	Feb 2019	CTSU CDSIC PM
Beta Release CDISC-compliant Rave-CTEP-AERS Integration ALS v4.0. <i>*Timeline dependent on CDISC SME Support</i>	Feb 2019	CDSIC PM
Perform CDISC Rave GLIB Impact Analysis.	March 2019	LPO
Manage IA updates to CDISC Rave GLIB.	April 2019	CTSU
Release CDISC Rave GLIB ALS to LPOs. Build Seed Study in collaboration with CDISC SME	Jul 2019	CTSU CTSU CDISC PM
Per NCI: All Groups to use CDISC Standards on all studies. *All CTEP IND Trials	Jan 2020	LPOs

Potential CDISC Workshop

- Needs of the LPOs?
- F2F or Series of Webinars

Questions?





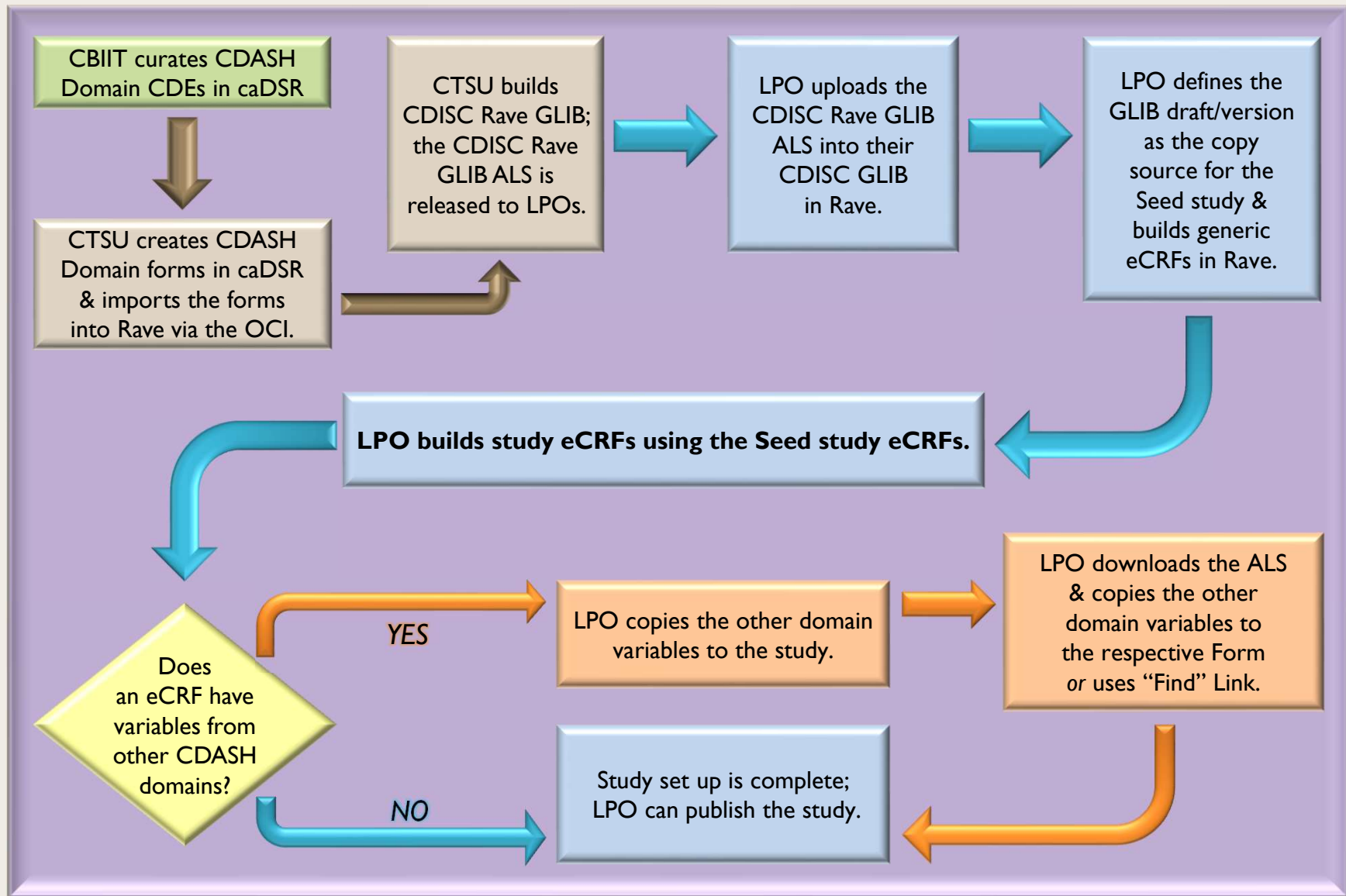
APPENDIX

CDISC IMPLEMENTATION WORKFLOW

CTSUS CHANGE MATRIX

ECRF BUILD SCENARIOS

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	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 **
Data Dictionary Name	Defined by CBIIT (e.g., CDISC_SDTM_RACE_PID6343345_V1_0F)	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., 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

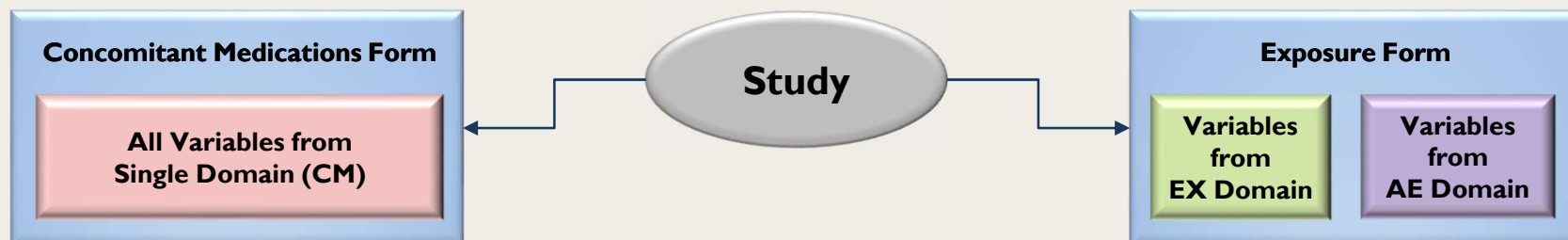
- Open the Exposure form; click add a new variable.
- Use the “**Find**” link on the variable definition screen to select the AE variable; click Apply to copy.

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 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][DASH=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][DASH=CMTRT][DASH=SDTM=CMTRT]

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

Start Date _____ dd-mmm-yyyy
[OID=CM_17_2011-10-24][DASH=CMSTDT]

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

End Date _____ dd-mmm-yyyy
[OID=CM_21_2011-10-24][DASH=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

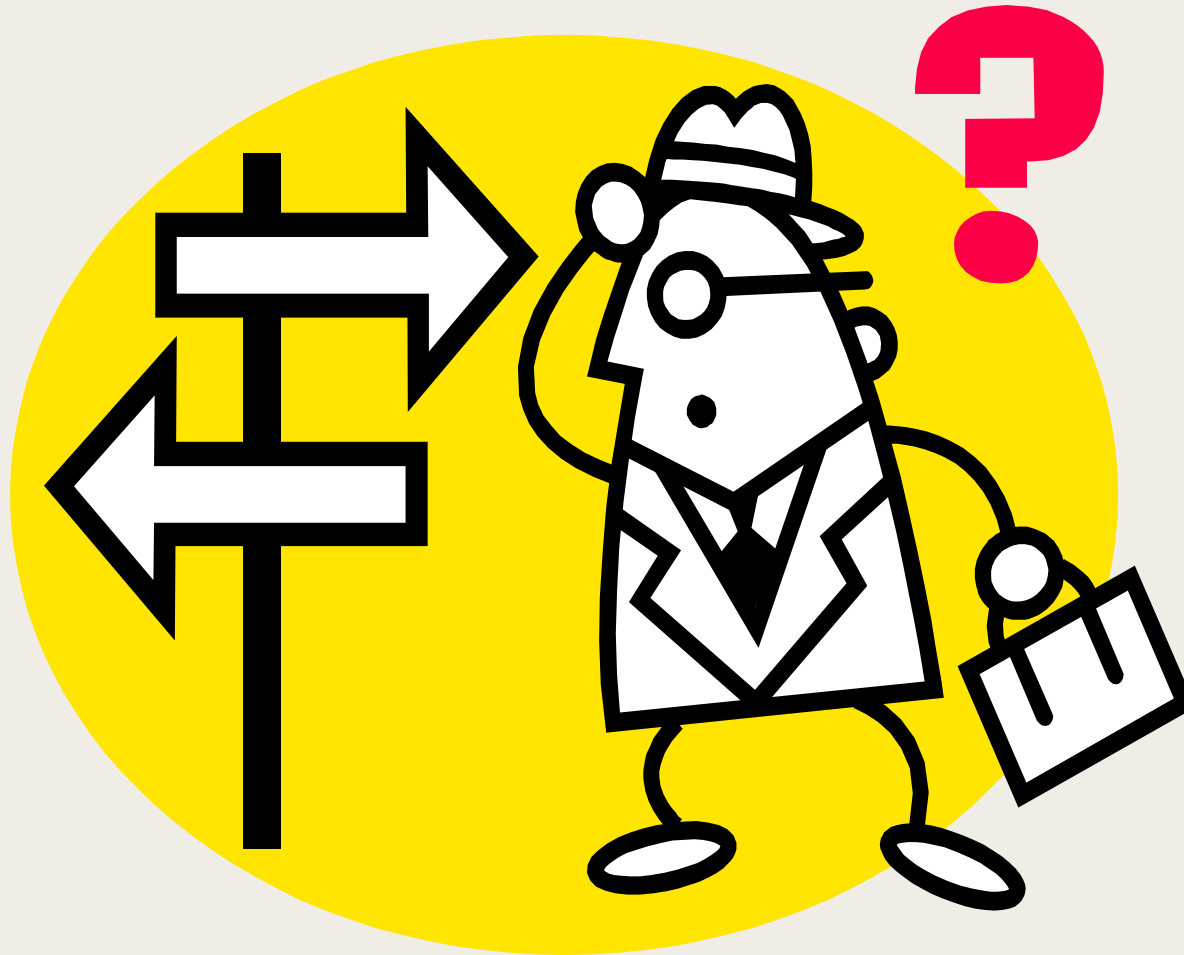
EXPOCCUR _____

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 _____

Questions?





APPENDIX: eCRF BUILD SCENARIOS

eCRFs Build Scenarios

- Rave eCRFs may have different build scenarios.
 - Variables from a single domain.
 - Variables from multiple domains.
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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.
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- Variables in the eCRF are from more than one domain.
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 - Follow the steps specified in the “eCRFs Build Scenarios: Single Domain” slide to build an Exposure form with variables from the EX domain.
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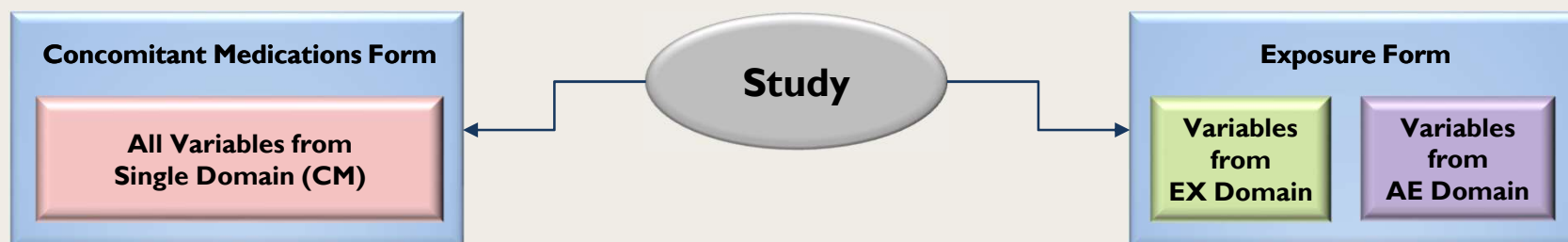
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[OID=CM_3_2011-10-24][DASH=CMTRT][DASH=SDTM=CMTRT]

Taken Prior to Study? [] NO [N] [] YES [Y]
[OID=CM_19_2011-10-24][DASH=CMPRIDR] [OID=CL_NY_SUB_Y_N_2011-10-24]

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

Ongoing [] NO [N] [] YES [Y]
[OID=CM_23_2011-10-24][DASH=CMONGO]

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

Exposure Form

EXSTDAT Start Date (dd- MMM- yyyy) _____

EXSTTIM Actual Start Time _____

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

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