Cancer Trials Support Unit
A SERVICE OF THE NATIONAL CANCER INSTITUTE

Linking practice to progress

CDISC RAVE GLOBAL LIBRARY
(CDASH, SDTM, CT)

FEBRUARY 27, 2019

Agenda

- CDISC Rave Global Library (GLIB)
- CDASH SDTM Domain
- Advantages of SDTM Variables
- CDISC Rave GLIB Standards
- Release Notes
- Demo
- Questions

CDISC Rave GLIB

- Versions used
  - CDASH – v2.0
  - SDTM – v3.3
  - CT – packages released by CDISC through 12/2018

- GLIB Components
  - Domain-specific forms (DM, AE, CM,….)
  - CDASH variables
  - SDTM variables with no direct mapping to CDASH
  - Control Terminology is attached to the variables

CDASH SDTM Domains

- CDISC Global library has 48 Domain/Forms
  - CDASH-SDTM domains = 26
  - SDTM-only domains = 22

  Note- Global library does not include Trial design domains (TA, TD, TE, TI, TM, TS, TV)

Advantages of SDTM Variables

- Ensure the data collected are consistent with what the sponsor expects to see in SDTM

- The safest, fastest way to build conformant SDTM is to collect what will be submitted

- Reduces mapping in submission program

CDISC Rave GLIB Standards: **Form Level**

Form Attributes	GLIB: CDASH Variables	GLIB: SDTM Variables	LPO can Modify during *Study Build*
Form Name	Domain Name *(Ex: Adverse Events)*	Domain Name *(Ex: Tumor/Lesion Results)*	Yes
Form OID	2 Letter Domain *(Ex: AE)*	2 Letter Domain *(Ex: TR)*	Yes

CDISC Rave GLIB Standards: **Field Level** *(1)*

Field Attributes	GLIB: CDASH Variables	GLIB: SDTM Variables	LPO can Modify during *Study Build*
Variable OID	CDASH variables from caDSR (CDE Short name)	SDTM variable from SDTM 3.3 Metadata table if no direct mapping of CDASH to SDTM available	No
Field Name	Variable Label + PID (caDSR)	Variable Label from SDTM 3.3 Metadata table	No
Field OID	CDASH variables from caDSR (CDE Short name)	SDTM variable from SDTM 3.3 Metadata table if no direct mapping of CDASH to SDTM available	No
Field Label	Question Text or Prompt (For Field with no labels, the Field label will be the Variable label from CDASH 2.0 Metadata table)	Variable Label from SDTM 3.3 Metadata table	Yes

CDISC Rave GLIB Standards: **Field Level** *(2)*

Field Attributes	GLIB: CDASH Variables	GLIB: SDTM Variables	LPO can Modify during *Study Build*
Format- Date	dd MMM yyyy	dd MMM yyyy	Yes
Format- Time	HH:nn:ss (24 hr)	HH:nn:ss (24 hr)	Yes
Format- Char (W Dictionary)	Same as caDSR	Max length of longest codelist submission term(Note- If variable exists in caDSR or same codelist being used across variables in caDSR, format followed as in caDSR, else followed this standard.)	Yes
Format- Char (W/O Dictionary)	Same as caDSR	$10 (Note- If variable exists in caDSR, format followed as in caDSR, else followed this standard.)	Yes
Format- Numeric	Same as caDSR	10 (Note - If variable exists in caDSR, format followed as in caDSR, else followed this standard.)	Yes

CDISC Rave GLIB Standards: **Field Level** *(3)*

Field Attributes	GLIB: CDASH Variables	GLIB: SDTM Variables	LPO can Modify during *Study Build*
Control Type	Text = Character or numeric variable with format <= 50 Long Text = Non-enumerated variables with format > $50 DATE/TIME = Date or time variable Dropdown = Variables having dictionary <=10 entries SearchList = Variables having dictionary > 10 entries	Text = Character or numeric variable with format <= 50 Long Text = Non-enumerated variables with format > $50 DATE/TIME = Date or time variable Dropdown = Variables having dictionary <=10 entries SearchList = Variables having dictionary > 10 entries	Yes
SAS Label	Variable Label from SDTM for direct mapping to SDTM, if no direct mapping SDTM variable or not in SDTM Model, CDASH variable label is used as SAS label	Variable Label from SDTM 3.3 Metadata table	No
Auto-Query for future Date	Checked for all dates	Checked for all dates	Yes

CDISC Rave GLIB Standards: **Dictionary Level**

Dictionary Attributes		GLIB: CDASH Variables	GLIB: SDTM Variables	LPO can Modify during *Study Build*
Data Dictionary Name		Submission value of the Codelist Name (Value Domain Short Name from caDSR)	Submission value of the Codelist Name from SDTM terminology file	No
Data Dictionary Values	User Data String	PV meaning from caDSR	NCI preferred term from SDTM Terminology file	No
	Coded Data String	PV from caDSR	Submission Value of the Codelist Term from SDTM terminology file	No

Release Notes

- CDISC Rave GLIB Content
- Provides two options to build study specific CRFs using CDISC Global library
  - CRF from single domain
  - CRF from multiple domains
- Creating custom domains and variables

Questions?