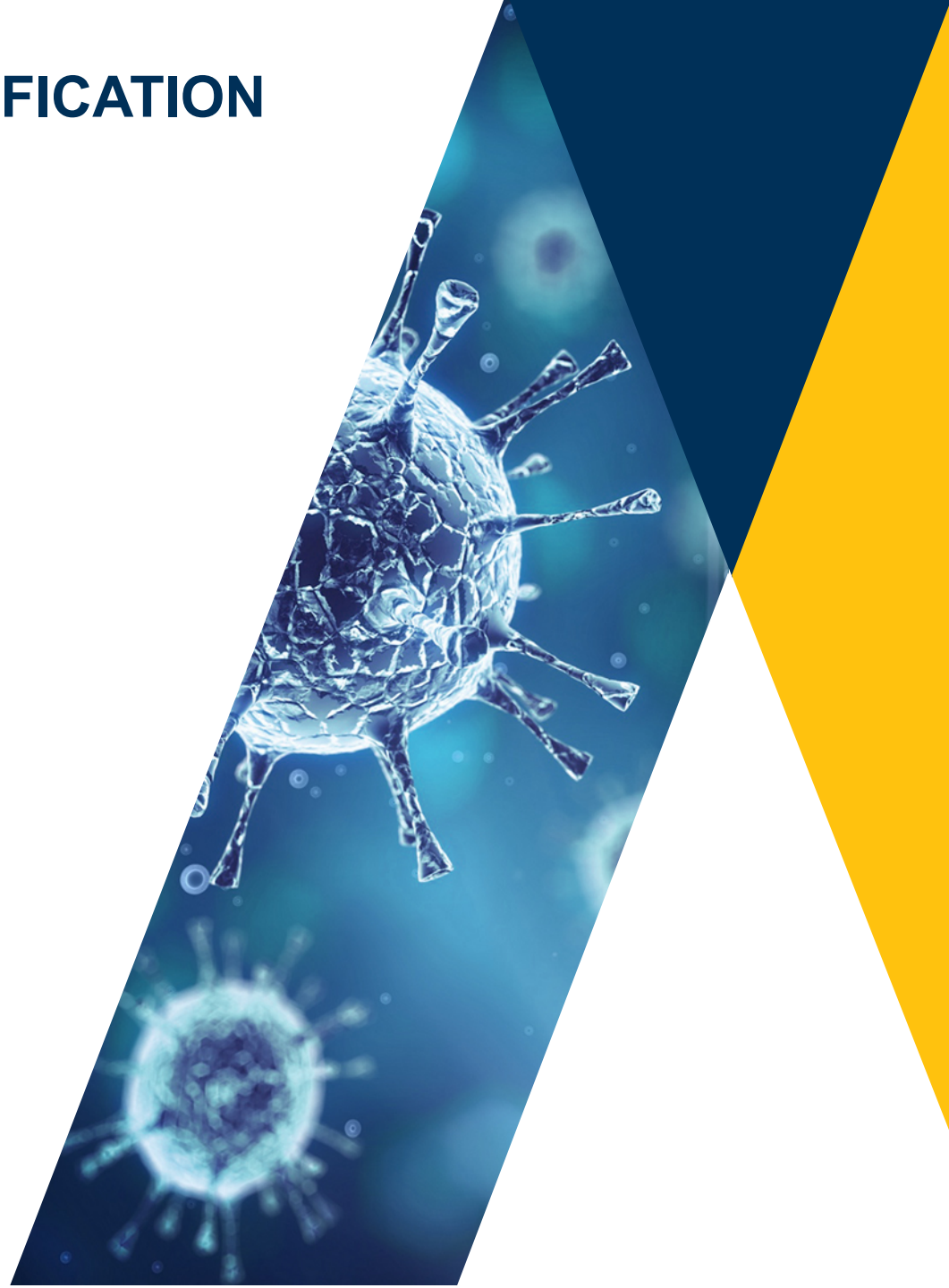


OPTIMIZING SDTM SPECIFICATION DEVELOPMENT WITH AUTO-POPULATION

Cori Kramer, Covance

Ryan Adalbert, Covance



Introduction

SNAP YOUR WAY TO ONESIE LEVEL EFFICIENCY



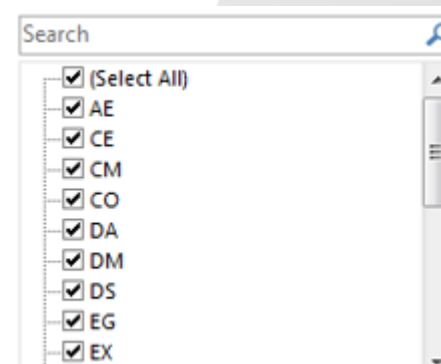
- Provide high level overviews of raw datasets
- Ensure all raw variables are mapped
- Increase speed of producing programming notes
- Eliminate need to check raw values against CT
- Ensure that certain variables conform as expected
- Produce uniform specification

Understanding Raw Data

OVERVIEW OF RAW DATASETS AND VARIABLES

Raw_Dataset ▾	Raw_Variable ▾
AE	AEPATT
AE	AEREL
AE	AESCONG
AE	AESDISAB
AE	AESDTH
AE	AESEQ
AE	AESER
AE	AESV
AE	AESHOSP
AE	AESLIFE
AE	AESMIE
AE	AESPID

Raw_Dataset ▾	Raw_Variable ▾
AE	AESTDTC
CE	CEDTC
CE	CEENDTC
CE	CESTDTC
CM	CMENDTC
CM	CMSTDTC
CO	CODTC
DA	DADTC
DM	BRTHDTC
DM	DMDTC
DM	DTHDTC
DM	RFENDTC



- Compile details of the variables from each dataset
- Excel can be used to sort and filter by each domain and or variable
- No Raw Variable Left Behind

Check Controlled Terminology

CHECKING RAW VALUES AGAINST CDISC CT

Raw_Dataset ▾	Raw_Variable ▾	Uniques ▾	Code ▾	Codelist_Code ▾	Codelist_Nam ▾	CDISC_Submission_Value ▾	CDISC_Synonym ▾
VS	VSPOS	NOT DONE (AFTER 5 MIN REST)				null	
VS	VSPOS	SITTING (AFTER 5 MIN REST)				SITTING	
VS	VSPOS	STANDING (AFTER 5 MIN REST)				STANDING	
VS	VSPOS	SUPINE (AFTER 5 MIN REST)				SUPINE	
VS	VSPOS	SITTING	C62122	C71148	Position	SITTING	Sitting
VS	VSPOS	STANDING	C62166	C71148	Position	STANDING	Standing
VS	VSPOS	SUPINE	C62167	C71148	Position	SUPINE	Supine

- View unique raw values next to the appropriate Controlled Terminology
- Values can be standardized to sponsor CT where necessary
- Can enter custom mapping instructions for each value

Check Raw Values For Conformance

CHECKING VARIABLE FORMATS

Raw_Dataset	Raw_Variable	Uniques
VS	VSDTC	yyyy-mm-dd

Raw_Dataset	Raw_Variable	Uniques
AE	USUBJID	###-####-####

- Check other variables for SDTM conformance that do not contain CT

Populate Specifications

SPECIFYING MAPPING INSTRUCTIONS

Raw_Dataset ▾	Raw_Variable ▾	Mapping_Instruction ▾
VS	VSDTC	Y

Raw_Dataset ▾	Raw_Variable ▾	Mapping_Instructions ▾
DM	DMDTC	Y
DM	DMDY	DY
DM	INVNAM	U
DM	RACE	Y
DM	RFENDTC	M
DM	RFSTDTC	M

- Indicate which variables should be mapped and how the mapping should be performed
- Use single character identifiers to specify which pre-programmed notes should be output to the specification

Populate Specifications

GENERATING SPECIFICATIONS

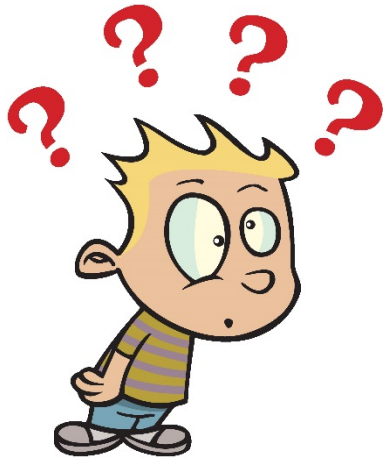
Dataset	Variable	Programming_Notes
VS	VSPOS	When VS.vspos = 'NOT DONE (AFTER 5 MIN REST)' set to missing When VS.vspos = 'SITTING (AFTER 5 MIN REST)' set to 'SITTING' When VS.vspos = 'STANDING (AFTER 5 MIN REST)' set to 'STANDING' When VS.vspos = 'SUPINE (AFTER 5 MIN REST)' set to 'SUPINE' Otherwise VS.vspos

- Macro reads in single character identifiers alongside the Controlled Terminology
- Macro then auto-populates the specification with the appropriate programming notes based on the user instructions

Concluding Thoughts

- Easily customizable to suit the needs of specific projects
- Excellent way to save time writing specs
- Helps reduce errors





Questions??

Cori Kramer

Work Phone: 484-942-4844

Email: cori.kramer@chiltern.com

Ryan Adalbert

Work Phone: 484-679-2541

Email: ryan.adalbert@chiltern.com

