Variable Requirements and Usage: Nicardipine

You can run Adverse Events Distribution with current dialog option selections.

Core Requirements

Used

For core (Load Data)

Variable(s) needed: ADSL.USUBJID and AE.USUBJID
Variable(s) used: ADSL.USUBJID and AE.USUBJID

Dialog Option Requirements

Used

For dialog option ("Merge supplemental domain" set to "Yes")

Variable(s) needed: AE.STUDYID
Variable(s) used: AE.STUDYID

For dialog option ("Select the analysis population" set to "Safety")

Variable(s) needed: ADSL.SAFFL or ADSL.SAFETY
Variable(s) used: ADSL.SAFFL
Note: SAFETY may be used in DM Supp.

For dialog option ("Treatment or Comparison Variable to Use" set to "Actual")

Variable(s) needed: ADSL.TRT01A or ADSL.ACTARM or ADSL.TRT01P or ADSL.ARM
Variable(s) used: ADSL.TRT01P
Note: Will attempt to use Planned treatment variables if Actual treatment variables not found. If ARM is missing, it will be created and set to "Blinded Treatment" so that certain reports can still be run.

Options

Missing

For core (Events Occurrence Check)

Variable(s) needed: AE.AEOCCUR
Variable(s) missing: AE.AEOCCUR
Note: Removes records with xxOCCUR = N

For output

Variable(s) needed: AE.EPOCH
Variable(s) missing: AE.EPOCH
Note: Variable will be available in Event Stacking, Data Filter, and Distributions.

Used

For core (Study Day Calculation)

Variable(s) needed: AE.AESTDY or (AE.AESTDTC and (ADSL.RFSTDTC or ADSL.TRTSDT))
Variable(s) used: AE.AESTDY
Note: Calculate relative Start Study Day variable STDY. Partial date imputes to first moment.

Options

Used

For core (Study Day Calculation)

Variable(s) needed: AE.AEENDY or AE.AEDUR or (AE.AEENDTC and (ADSL.RFSTDTC or ADSL.TRTSDT))

Variable(s) used: AE.AEENDY

Note: If ENDY cannot be calculated, set to STDY.

For dialog option ("Merge supplemental domain" set to "Yes")

Variable(s) needed: AE.DOMAIN

Variable(s) used: AE.DOMAIN

Note: Additional requirements of domain depend on IDVAR values of SUPP file

For output

Variable(s) needed: ADSL.AGE

Variable(s) used: ADSL.AGE

Note: Variable will be available in Data Filter and Distributions.

Variable(s) needed: ADSL.SEX

Variable(s) used: ADSL.SEX

Note: Variable will be available in Demographic Grouping, Data Filter, and Distributions.

Variable(s) needed: ADSL.RACE

Variable(s) used: ADSL.RACE

Note: Variable will be available in Demographic Grouping, Data Filter, and Distributions.

Variable(s) needed: ADSL.SITEID

Variable(s) used: ADSL.SITEID

Note: Variable will be available in Demographic Grouping, Data Filter, and Distributions.

Variable(s) needed: ADSL.COUNTRY

Variable(s) used: ADSL.COUNTRY

Note: Variable will be available in Demographic Grouping, Data Filter, and Distributions.

Variable(s) needed: ADSL.STUDYID

Variable(s) used: ADSL.STUDYID

Note: Use like other demography only if multiple levels deteced indicating a multi-study analysis.

Variable(s) needed: AE.AESER

Variable(s) used: AE.AESER

Note: Used in AE Stacking and Data Filter to categorize serious events.

Variable(s) needed: AE.AESEV or AE.AETOXGR

Variable(s) used: AE.AESEV

Note: Used in AE Stacking and Data Filter to categorize events by severity/toxicity.

Variable(s) needed: AE.AEREL

Variable(s) used: AE.AEREL

Note: Used in AE Stacking and Data Filter to categorize events by causality.

Variable(s) needed: AE.AEOUT

Variable(s) used: AE.AEOUT

Note: Used in AE Stacking and Data Filter to categorize events by their outcome.

Variable(s) needed: AE.AEACN

Options

Used

For output

Variable(s) used: AE.AEACN

Note: Used in AE Stacking and Data Filter to categorize events by action taken.