Data source

File: tran2.xptDate: 2017-09-11

Data definitions

- 1. C
- commented rows
- values: ., C
- 2. USUBJID
 - universal subject identifier
- 3. ID
 - NONMEM ID number
- 4. EVID
 - event ID indicator
 - comment: per NONMEM specifications
- 5. MDV
 - missing DV indicator
 - comment: per NONMEM specifications
- 6. SEQ
 - record type indicators
 - values: 1 = concentration, 2 = response, 3 = other
- 7. AMT
 - dose amount
 - unit: mg
- 8. II
 - interdose interval
 - unit: hours
- 9. CMT
 - compartment number
 - short name: Compartment
 - values: 1, 2, 3, 4
 - comment: per NONMEM specifications
- 10. TAFD
 - time after first dose
 - unit: hours
- 11. WT
 - baseline weight
 - short name: Weight
 - unit: kg
- 12. **EGFR**
 - estimated glomerular filtration rate
 - short name: eGFR

- unit: ml/min/1.73 m2
- if_missing: imputed

13. STUDY

- study identifier
- short name: Study
- values:
 - -100 = The first phase 1 study
 - 202 = The first phase 2 study conducted only at sites 1, 2, 3 when the formulation was still oral liquid only
 - -303 = The renal impairment study
 - 203 = The second phase 2 study

$14. \, \text{SEX}$

• values: 0 = male, 1 = female

15. BQL

- DV value is below the quantitation limit
- short name: below limit of quantification
- values: 0 = FALSE, 1 = TRUE

16. DV

- dependent variable
 - NoDoze concentration ng/mL when SEQ==1
 - Alertness when SEQ==2
 - BMI kg/m2 when SEQ==3
- comment: see SEQ

17. DV2

- second dependent variable
 - NoDoze concentration ng/mL
 - Alertness
 - BMI kg/m2

18. HAIR

- patient hair color
- values: 0 = brown, 1 = blonde, 2 = black

19. CLCR

- short name: creatinine clearance
- unit: ml/min
- derivation: (140-AGE)*IBW/SCR; x 0.85 if female
- if_missing: dropped