Data source

Data Set: specDate: 2018-01-03

Data definitions

- 1. C
- commented rows
- numeric
- values: ., C
- 2. USUBJID
 - universal subject identifier
 - numeric
- 3. ID
 - NONMEM ID number
 - numeric
- 4. EVID
 - event ID indicator
 - numeric
 - comment: per NONMEM specifications
- 5. MDV
 - missing DV indicator
 - numeric
 - comment: per NONMEM specifications
- 6. SEQ
 - record type indicators
 - \bullet numeric
 - values: 1 = concentration, 2 = response, 3 = other
- 7. AMT
 - dose amount
 - short name: Amount
 - numeric
 - unit: mg
- 8. II
 - interdose interval
 - numeric
 - unit: hours
- 9. **CMT**
 - compartment number
 - short name: Compartment
 - numeric
 - values: 1, 2, 3, 4
 - comment: per NONMEM specifications

10. TAFD

- time after first dose
- numeric
- unit: hours

11. WT

- baseline weight
- short name: Weight
- numeric
- unit: kg

12. **EGFR**

- estimated glomerular filtration rate
- short name: eGFR
- numeric
- unit: ml/min/1.73 m2
- if_missing: imputed

13. STUDY

- study identifier
- short name: Study
- numeric
- 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. SEX

- numeric
- values: 0 = male, 1 = female

15. BQL

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

16. **DV**

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

17. DV2

- second dependent variable
- numeric
 - NoDoze concentration ng/mL
 - Alertness NULL

$-\ \mathrm{BMI}\ kg/m2$

18. **HAIR**

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

19. CLCR

- short name: creatinine clearance
- numeric
- unit: ml/min
- if_missing: dropped