

Data source

- File: tran2.xpt
- Date: 2017-09-05

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
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. **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