

DEM104101 PK/PD Analysis Data sets

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Dataset: DEM104101F_PK

The population PK analysis data set

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

Dataset: DEM104101F_PKPD

The population PK/PD analysis data set

1. **C**
 - commented rows
 - values: ., C
2. **MDV**
 - missing DV indicator
 - comment: per NONMEM specifications
3. **SEQ**
 - record type indicators
 - values: 1 = concentration, 2 = response, 3 = other
4. **AMT**
 - dose amount
 - unit: mg
5. **II**
 - interdose interval
 - unit: hours
6. **CMT**
 - compartment number
 - short name: Compartment
 - values: 1, 2, 3, 4
 - comment: per NONMEM specifications

7. **TAFD**
 - time after first dose
 - unit: **hours**
8. **WT**
 - baseline weight
 - short name: Weight
 - unit: **kg**
9. **EGFR**
 - estimated glomerular filtration rate
 - short name: eGFR
 - unit: **ml/min/1.73 m2**
 - if_missing: imputed

Dataset: DEM104101F__AE

Adverse event analysis data set

1. **C**
 - commented rows
 - values: ., C
2. **MDV**
 - missing DV indicator
 - comment: per NONMEM specifications
3. **SEQ**
 - record type indicators
 - values: 1 = concentration, 2 = response, 3 = other
4. **AMT**
 - dose amount
 - unit: **mg**
5. **II**
 - interdose interval
 - unit: **hours**
6. **CMT**
 - compartment number
 - short name: Compartment
 - values: 1, 2, 3, 4
 - comment: per NONMEM specifications
7. **TAFD**
 - time after first dose
 - unit: **hours**
8. **WT**
 - baseline weight
 - short name: Weight
 - unit: **kg**
9. **EGFR**
 - estimated glomerular filtration rate
 - short name: eGFR
 - unit: **ml/min/1.73 m2**
 - if_missing: imputed