

# DEM104101 PK/PD Analysis Data sets

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- **DEM104101F\_\_PK.xpt** The population PK analysis data set
- **DEM104101F\_\_PKPD.xpt** The population PK/PD analysis data set
- **DEM104101F\_\_AE.xpt** Adverse event analysis data set

## 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