



CONFIDENTIAL

Analysis data specification

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1 analysis1

Description: Example PopPK analysis data set.

| Column | Type | Field | Value |
|--------|-----------|---------------------------------|--|
| C | character | short-name values | comment character . = analysis row, C = commented row |
| NUM | numeric | short-name | record number |
| ID | numeric | short-name | subject identifier |
| SUBJ | character | short-name | subject identifier |
| TIME | numeric | short-name unit | time after first dose hour |
| SEQ | numeric | short-name values | data type 0 = observation, 1 = dose |
| CMT | numeric | short-name | compartment number |
| EVID | numeric | short-name values | event ID 0, 1 |
| AMT | numeric | short-name unit | dose amount mg |
| DV | numeric | short-name unit | dependent variable $\mu\text{g/L}$ |
| AGE | numeric | short-name unit | age years |
| WT | numeric | short-name unit | weight kg |
| CRCL | numeric | short-name unit | creatinine clearance ml/min |
| ALB | numeric | short-name unit long-name | albumin g/dL serum albumin |
| BMI | numeric | short-name unit long-name | BMI m ² /kg body mass index |
| AAG | numeric | short-name unit | alpha-1-acid glycoprotein mg/dL |
| SCR | numeric | short-name unit | serum creatinine mg/dL |
| AST | numeric | short-name | aspartate aminotransferase |
| ALT | numeric | short-name | alanine aminotransferase |
| HT | numeric | short-name unit long-name | height cm Height |

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| Column | Type | Field | Value |
|--------|-----------|--|--|
| CP | numeric | short-name values | Child-Pugh score 0 = normal, 1 = Pugh1, 2 = Pugh2, 3 = Pugh3 |
| TAFD | numeric | short-name unit | time after first dose hours |
| TAD | numeric | short-name unit | time after dose hours |
| LDOS | numeric | short-name unit | last dose amount mg |
| MDV | numeric | short-name values long-name comment | MDV 0, 1 missing DV indicator per NONMEM specifications |
| BLQ | numeric | short-name values | below limit of quantification 1, 0 |
| PHASE | numeric | short-name values | study phase indicator 1 |
| STUDY | numeric | short-name values | study number 1 = SAD, 2 = MAD, 3 = Renal, 4 = Hepatic |
| RF | character | short-name values | renal function stage norm = Normal, mild = Mild, mod = Moderate, sev = Severe |

2 DEM104101F_PKPD

Description: Population PKPD analysis data set

| Column | Type | Field | Value |
|--------|-----------|--|--|
| C | character | short-name values long-name | C ., C commented rows |
| MDV | numeric | short-name long-name comment | MDV missing DV indicator per NONMEM specifications |
| SEQ | numeric | short-name values long-name | SEQ 1 = concentration, 2 = response, 3 = other record type indicators |
| AMT | numeric | short-name unit range long-name | AMT mg 0 to 1000 dose amount |
| II | numeric | short-name unit long-name | II hours interdose interval |
| CMT | numeric | short-name values long-name comment | Compartment 1, 2, 3, 4 compartment number per NONMEM specifications |

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| Column | Type | Field | Value |
|--------|---------|--|---|
| TAFD | numeric | short-name unit long-name | TAFD hours time after first dose |
| WT | numeric | short-name unit range long-name | Weight kg 40 to 100 baseline weight |
| EGFR | numeric | short-name unit range long-name | eGFR ml/min/1.73 m2 10 to 300 estimated glomerular filtration rate |
| SEX | numeric | short-name values | SEX 0 = male, 1 = female |