

Data Definitions

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1 Datasets

| Description | Location |
|---------------------------------|---------------|
| Example PopPK analysis data set | analysis3.xpt |

1.1 Example PopPK analysis data set (analysis3.xpt)

| VARIABLE | LABEL | TYPE | CODES |
|----------|--|-----------|--|
| C | comment character | character | C = comment, . = non-comment |
| NUM | record number | numeric | |
| ID | subject identifier | numeric | |
| TIME | time after first dose (unit: hour) | numeric | |
| SEQ | data type | numeric | 0 = dose, 1 = observation |
| CMT | compartment number | numeric | |
| EVID | event ID | numeric | 0 = observation, 1 = dose |
| AMT | dose amount (unit: mg) | numeric | |
| DV | dependent variable | numeric | |
| AGE | age (unit: years) | numeric | |
| WT | weight (unit: kg) | numeric | |
| HT | height (unit: cm) | numeric | |
| EGFR | estimated glomerular filtration rate (unit: mL/min/1.73m ²) | numeric | |
| ALB | albumin (unit: g/dL) | numeric | |
| BMI | body mass index (unit: m ² /kg) | numeric | |
| SEX | SEX | numeric | 0 = male, 1 = female |
| AAG | alpha-1-acid glycoprotein (unit: mg/dL) | numeric | |
| SCR | serum creatinine (unit: mg/dL) | numeric | |
| AST | aspartate aminotransferase | numeric | |
| ALT | alanine aminotransferase | numeric | |
| CP | Child-Pugh score | numeric | 0 = normal, 1 = score=1, 2 = score=2, 3 = score=3 |
| TAFD | time after first dose (unit: hour) | numeric | |
| TAD | time after dose (unit: hour) | numeric | |
| LDOS | last dose amount (unit: mg) | numeric | |
| MDV | missing DV indicator | numeric | 0 = non-missing, 1 = missing |
| BLQ | below limit of quantification | numeric | 1 = above QL, 0 = below QL |
| PHASE | study phase indicator | numeric | values: 1 |

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| VARIABLE | LABEL | TYPE | CODES |
|----------|---------------------------|-----------|---|
| STUDYN | study number | numeric | values: 1, 2, 3, 4 |
| DOSE | nominal dose amount | numeric | 5 = 5 mg, 10 = 10 mg, 25 = 25 mg, 50 = 50 mg, 75 = 75 mg, 100 = 100 mg, 150 = 150 mg, 200 = 200 mg |
| SUBJ | subject identifier | character | |
| USUBJID | unique subject identifier | character | |
| STUDY | study name | character | values: 101-DEMO-001, 101-DEMO-002, 201-DEMO-003, 201-DEMO-004 |
| ACTARM | treatment arm | character | values: DEMO 5 mg, DEMO 10 mg, DEMO 10 mg qd x7, DEMO 25 mg, DEMO 25 mg qd x7, DEMO 50 mg qd x7, DEMO 75 mg qd x7, DEMO 100 mg, DEMO 100 mg qd x7, DEMO 150 mg, DEMO 200 mg |
| RF | renal function stage | character | norm = normal, mild, mod = moderate, sev = severe |