



CONFIDENTIAL

Analysis data specification

2019-01-14

Author:

Michelle Johnson
Metrum Research Group LLC
Tunxis Road, Suite 112
Tariffville, CT 06081

1 Datasets

| Description | Location |
|---|--------------------------------------|
| an example data set | example_data_set.xpt |
| Population PKPD analysis data set | DEM104101F_PKPD.xpt |

1.1 an example data set (spec.xpt)

| VARIABLE | LABEL | TYPE | CODES |
|----------|--|-----------|--|
| C | commented rows | character | values: ., C |
| USUBJID | universal subject identifier | character | |
| ID | NONMEM ID number | numeric | |
| EVID | event ID indicator | numeric | |
| MDV | missing DV indicator | numeric | |
| SEQ | record type indicators | numeric | 1 = concentration, 2 = response, 3 = other |
| AMT | dose amount (unit: mg) | numeric | |
| II | interdose interval (unit: hours) | numeric | |
| CMT | compartment number | numeric | values: 1, 2, 3, 4 |
| TAFD | time after first dose (unit: hours) | numeric | |
| WT | baseline weight (unit: kg) | numeric | |
| EGFR | estimated glomerular filtration rate (unit: ml/min/1.73m2) | numeric | |
| STUDY | study identifier | character | 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 |
| SEX | SEX | numeric | 0 = male, 1 = female |
| BQL | DV value is below the quantitation limit | numeric | 0 = FALSE, 1 = TRUE |
| DV | dependent variable (unit: ng/mL) | numeric | |
| DV2 | second dependent variable | numeric | |
| HAIR | patient hair color | character | 0 = brown, 1 = blonde, 2 = black |
| CLCR | creatinine clearance (unit: ml/min) | numeric | |
| ALB | adjusted albumin (unit: g/dL) | numeric | |

1.2 Population PKPD analysis data set (DEM104101F_PKPD.xpt)

| VARIABLE | LABEL | TYPE | CODES |
|----------|----------------|-----------|--------------|
| C | commented rows | character | values: ., C |

Continued on next page

| VARIABLE | LABEL | TYPE | CODES |
|----------|--|---------|---|
| MDV | missing DV indicator | numeric | |
| SEQ | record type indicators | numeric | 1 = concentration, 2 = response, 3 = other |
| AMT | dose amount (unit: mg) | numeric | |
| II | interdose interval (unit: hours) | numeric | |
| CMT | compartment number | numeric | values: 1, 2, 3, 4 |
| TAFD | time after first dose (unit: hours) | numeric | |
| WT | baseline weight (unit: kg) | numeric | |
| EGFR | estimated glomerular filtration rate (unit: ml/min/1.73 m2) | numeric | |
| SEX | SEX | numeric | 0 = male, 1 = female |