



CONFIDENTIAL

Data Definitions

2018-01-08

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1 Datasets

| Description | Location |
|------------------------------------|---------------------|
| Population PK analysis data set | DEM104101F_PK.xpt |
| Population PK/PD analysis data set | DEM104101F_PKPD.xpt |
| AE analysis data set | DEM104101F_AE.xpt |

1.1 Population PK analysis data set (DEM104101F_PK.xpt)

| VARIABLE | LABEL | TYPE | CODES |
|----------|------------------------------|-----------|--------------------------------|
| C | commented rows | character | . = not a comment, C = comment |
| USUBJID | universal subject identifier | character | |
| ID | NONMEM ID number | character | |
| EVID | event ID indicator | numeric | |
| WT | WT | numeric | |

1.2 Population PK/PD analysis data set (DEM104101F_PKPD.xpt)

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

1.3 AE analysis data set (DEM104101F_AE.xpt)

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

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| VARIABLE | LABEL | TYPE | CODES |
|----------|---|---------|-------|
| 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 | |