DEM104101 PK/PD Analysis Data Sets

MetrumRG

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1 DEM104101F_PK

Description: Population PK analysis data set

| Column | Туре | Field | Value |
|---------|-----------|------------|--------------------------------|
| C | character | unit | |
| | | short-name | С |
| | | long-name | commented rows |
| | | values | . = not a comment, C = comment |
| USUBJID | character | unit | |
| | | short-name | USUBJID |
| | | long-name | universal subject identifier |
| ID | character | unit | |
| | | short-name | ID |
| | | long-name | NONMEM ID number |
| EVID | numeric | unit | |
| | | short-name | EVID |
| | | long-name | event ID indicator |
| | | comment | per NONMEM specifications |
| WT | numeric | unit | |
| | | short-name | WT |
| | | range | 2 to 4 |

2 DEM104101F_PKPD

Description: Population PK/PD analysis data set

| Column | Туре | Field | Value |
|--------|-----------|---|------------------|
| C | character | unit short-name long-name values | C commented rows |

| Column | Type | Field | Value |
|--------|---------|------------|--|
| MDV | numeric | unit | |
| | | short-name | MDV |
| | | long-name | missing DV indicator |
| | | comment | per NONMEM specifications |
| SEQ | numeric | unit | • |
| | | short-name | SEQ |
| | | long-name | record type indicators |
| | | values | 1 = concentration, 2 = response, 3 = other |
| AMT | numeric | unit | mg |
| | | short-name | AMT |
| | | long-name | dose amount |
| | | range | 0 to 1000 |
| II | numeric | unit | hours |
| | | short-name | II |
| | | long-name | interdose interval |
| CMT | numeric | unit | |
| | | short-name | Compartment |
| | | long-name | compartment number |
| | | comment | per NONMEM specifications |
| | | values | 1, 2, 3, 4 |
| TAFD | numeric | unit | hours |
| | | short-name | TAFD |
| | | long-name | time after first dose |
| WT | numeric | unit | kg |
| | | short-name | Weight |
| | | long-name | baseline weight |
| | | range | 40 to 100 |
| EGFR | numeric | unit | ml/min/1.73 m2 |
| | | short-name | eGFR |
| | | long-name | estimated glomerular filtration rate |
| | | range | 10 to 300 |
| SEX | numeric | unit | |
| | | short-name | SEX |
| | | values | 0 = male, 1 = female |

3 DEM104101F_AE

Description: AE analysis data set

| Column | Туре | Field | Value |
|--------|-----------|--|--|
| С | character | unit short-name long-name values | C commented rows ., C |
| MDV | numeric | unit short-name long-name comment | MDV missing DV indicator per NONMEM specifications |

| Column | Type | Field | Value |
|--------|---------|------------|--|
| SEQ | numeric | unit | |
| | | short-name | SEQ |
| | | long-name | record type indicators |
| | | values | 1 = concentration, $2 = $ response, $3 = $ other |
| AMT | numeric | unit | mg |
| | | short-name | AMT |
| | | long-name | dose amount |
| | | range | 0 to 1000 |
| II | numeric | unit | hours |
| | | short-name | II |
| | | long-name | interdose interval |
| CMT | numeric | unit | |
| | | short-name | Compartment |
| | | long-name | compartment number |
| | | comment | per NONMEM specifications |
| | | values | 1, 2, 3, 4 |
| TAFD | numeric | unit | hours |
| | | short-name | TAFD |
| | | long-name | time after first dose |
| WT | numeric | unit | kg |
| | | short-name | Weight |
| | | long-name | baseline weight |
| | | range | 40 to 100 |
| EGFR | numeric | unit | ml/min/1.73 m2 |
| | | short-name | eGFR |
| | | long-name | estimated glomerular filtration rate |
| | | range | 10 to 300 |