

Data Specification

MetrumRG

2019-01-14 19:49:07

spec

Description: an example data set

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

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| Column | Type | Field | Value |
|--------|-----------|--|---|
| STUDY | character | short-name values | Study 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 |
| | | long-name | study identifier |
| SEX | numeric | short-name values | SEX 0 = male, 1 = female |
| BQL | numeric | short-name values long-name | below limit of quantification 0 = FALSE, 1 = TRUE DV value is below the quantitation limit |
| DV | numeric | short-name unit long-name comment | DV ng/mL dependent variable see SEQ |
| DV2 | numeric | short-name long-name | DV2 second dependent variable |
| HAIR | character | short-name values long-name | HAIR 0 = brown, 1 = blonde, 2 = black patient hair color |
| CLCR | numeric | short-name unit range | creatinine clearance ml/min 40 to 180 |
| ALB | numeric | short-name unit range comment | adjusted albumin g/dL 1 to 5 in the lookup document as ALB2 |