Dataset name, description, and location

|  |  |  |
| --- | --- | --- |
| NAME | DESCRIPTION | LOCATION |
| data | General analysis dataset | material/01-01-DataProgAnal/dataNLME01/data.xpt |

DATA specification

Missing values are coded in the dataset as '.' and referenced in this specification as 'NA'.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| NAME | TYPE | LABEL | VALUES | COMMENTS |
| IXGDF | Numeric | Index of record in master dataset | 1...N |  |
| IGNORE | String | Exclusion reason | Reason for ignoring an observation record in the analysis. If NA then the record is not ignored |  |
| USUBJID | String | Unique subject identifier | Unique subject ID or a derivative of it, allowing to identify the subject |  |
| ID | Numeric | Numeric subject ID for modeling software | Numeric subject ID for modeling software |  |
| STUDY | String | Short study name/number | FIH, FIH:::extension |  |
| STUDYN | Numeric | Study | 1 (FIH), 2 (FIH extension) |  |
| TRTNAME | String | Name actual treatment given to subject | 100mg:::oral:::single:::dose, 10mg:::oral:::single:::dose, 1mg:::oral:::single:::dose, 200mg:::oral:::single:::dose, 20mg:::oral:::single:::dose, 2mg:::oral:::single:::dose, 50mg:::oral:::single:::dose, 5mg:::oral:::single:::dose |  |
| TRT | Numeric | TRTNAME | 9 (Placebo), 3 (1mg oral single dose), 6 (2mg oral single dose), 8 (5mg oral single dose), 2 (10mg oral single dose), 5 (20mg oral single dose), 7 (50mg oral single dose), 1 (100mg oral single dose), 4 (200mg oral single dose) |  |
| TIME | Numeric | Actual time relative to first dose | 'TIME' values in the unit defined in the 'TIMEUNIT' column |  |
| TIMEPOS | Numeric | Time since first record in subject | 'TIMEPOS' values in the unit defined in the 'TIMEUNIT' column |  |
| NT | Numeric | Nominal event time | 'NT' values in the unit defined in the 'TIMEUNIT' column. Can be 'NA' if value is undefined |  |
| TAD | Numeric | Time after last dose | 'TAD' values in the unit defined in the 'TIMEUNIT' column |  |
| TIMEUNIT | String | Unit of all numeric time definitions | 'HOURS' |  |
| YTYPE | Numeric | Observation output number | 1 (Plasma:::concentration:::IQ0815),0 or NA (non-observation records) |  |
| NAME | String | Short name of event | Dose:::IQ0815, Plasma:::concentration:::IQ0815 |  |
| VALUE | Numeric | Value of event defined by NAME | 'VALUE' values in the unit defined in the 'UNIT' column for the same record |  |
| DV | Numeric | Dependent variable | 0 for dosing events.For observation events the value of the observation in the units defined in the 'UNIT' column of this record.Missing observations are coded as 'NA'.For observations below the 'LLOQ' the value is set to the 'LLOQ' for handling the M3 or M4 method in the modeling. |  |
| UNIT | String | Unit of the value | 'NA': if undefined or information not available / not needed for analysis |  |
| LLOQ | Numeric | Lower limit of quantification | In units as defined in the 'UNIT' column of the same record. 'NA': if undefined or information not available / not needed for analysis |  |
| CENS | Numeric | Censoring flag | 1 for observation records below 'LLOQ' if handling in the model via the M3 or M4 method. 0 otherwise |  |
| MDV | Numeric | Missing dependent variable flag | 1 for dosing records and ignored observation records, 0 otherwise |  |
| EVID | Numeric | Event ID | 1 for dosing records, 0 for non-dosing records |  |
| AMT | Numeric | Dose amount (mg) | Dose given in the unit of the 'UNIT' column of this record. 0 for non-dosing records |  |
| ADM | Numeric | Administration input number | 1 (Dose:::IQ0815),0 or NA (non-dose records) |  |
| II | Numeric | Interval of dosing | In units as defined in the 'UNIT' column of the same record. '0': if undefined (non-dosing events) or information not available / not needed for analysis |  |
| ADDL | Numeric | Number of addl doses with II interval | '0': if undefined (non-dosing events) or information not available / not needed for analysis |  |
| ROUTE | String | Route of administration | ORAL. 'NA' for non-dosing records |  |
| TINF | Numeric | Infusion time | Duration of dose administration / infusion time for dosing records. 0 indicates a bolus admnistration or a non-dosing record |  |
| RATE | Numeric | Rate of infusion | Rate of dose administration for dosing records. 0 indicates a bolus admnistration or a non-dosing record |  |
| DOSE | Numeric | DOSE of last dose (carry-forward) | In units as defined in the 'UNIT' column of current dose record. 0 for pre-first dose records in a subject |  |
| CENTER | Numeric | Center number | See 'LABEL' column |  |
| VISIT | Numeric | Visit number | 'NA' if undefined or information not available / not needed for analysis |  |
| DURATION | Numeric | Duration of event | 'DURATION' values in the unit defined in the 'TIMEUNIT' column. -1 if event ongoing post end of observation period |  |
| WT0 | Numeric | Baseline Bodyweight (kg) | See 'LABEL' column |  |
| AGE0 | Numeric | Baseline Age (Years) | See 'LABEL' column |  |
| HT0 | Numeric | Baseline Height (cm) | See 'LABEL' column |  |
| SEX | Numeric | Gender | 1 (male) |  |