Dataset name, description, and location

|  |  |  |
| --- | --- | --- |
| NAME | DESCRIPTION | LOCATION |
| dataNLME | General analysis dataset | Data/dataNLME.xpt |

DATANLME 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 |  |
| 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 |  |
| TAD | Numeric | Time after last dose | 'TAD' values in the unit defined in the 'TIMEUNIT' column |  |
| TIMEUNIT | String | Unit of all numeric time definitions | 'DAYS' |  |
| YTYPE | Numeric | Observation output number | 1 (HS0815:::Concentration),0 or NA (non-observation records) |  |
| NAME | String | Short name of event | HS0815:::Concentration, HS0815:::Dose |  |
| 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'. |  |
| 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 (HS0815:::Dose),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 | IV. '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 |  |
| DURATION | Numeric | Duration of event | 'DURATION' values in the unit defined in the 'TIMEUNIT' column. -1 if event ongoing post end of observation period |  |
| OCC | Numeric | Index of different occasions for IOV | Integer indices, each unique index coding for a distinct occasion to consider in IOV modeling |  |