Dataset name, description, and location

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| NAME | DESCRIPTION | LOCATION |
| data | General analysis dataset | ../02-Data/02\_dataNLME\_M1/data.xpt |

DATA specification

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

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| 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 | X3401, X3402 |  |
| STUDYN | Numeric | Study | 1 (X3401), 2 (X3402) |  |
| TRTNAME | String | Name actual treatment given to subject | 100mg:::oral:::daily:::dosing:::for:::28:::days, 100mg:::oral:::single:::dose, 10mg:::oral:::daily:::dosing:::for:::28:::days, 10mg:::oral:::single:::dose, 1mg:::oral:::single:::dose, 200mg:::oral:::single:::dose, 20mg:::oral:::daily:::dosing:::for:::28:::days, 20mg:::oral:::single:::dose, 2mg:::oral:::single:::dose, 50mg:::oral:::daily:::dosing:::for:::28:::days, 50mg:::oral:::single:::dose, 5mg:::oral:::single:::dose |  |
| TRT | Numeric | TRTNAME | 13 (Placebo), 5 (1mg oral single dose), 9 (2mg oral single dose), 12 (5mg oral single dose), 4 (10mg oral single dose), 8 (20mg oral single dose), 11 (50mg oral single dose), 2 (100mg oral single dose), 6 (200mg oral single dose), 3 (10mg oral daily dosing for 28 days), 7 (20mg oral daily dosing for 28 days), 10 (50mg oral daily dosing for 28 days), 1 (100mg oral daily dosing for 28 days) |  |
| 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:::HS02),0 or NA (non-observation records) |  |
| NAME | String | Short name of event | Dose:::HS02, Plasma:::concentration:::HS02 |  |
| 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 (Dose:::HS02),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 |  |
| INDNAME | String | Indication name | Healthy:::Volunteers |  |
| IND | Numeric | Numeric indication flag | 1 (INDNAME=Healthy:::Volunteers) |  |
| COMPOUND | String | Name of the studied compound | HS02 |  |
| VISIT | Numeric | Visit number | 'NA' if undefined or information not available / not needed for analysis |  |
| VISNAME | String | Visit name | 'UNKNOWN': if undefined or information not available / not needed for analysis |  |
| DATEDAY | String | Start date of event | 'UNKNOWN': if undefined or information not available / not needed for analysis |  |
| DATETIME | String | Start time of event | 'UNKNOWN': 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 |  |
| TYPENAME | String | Type of event | Concentration, Dose |  |
| AGE | Numeric | Baseline Age (Years) | See 'LABEL' column |  |
| WT0 | Numeric | Baseline Bodyweight (kg) | See 'LABEL' column |  |
| HT0 | Numeric | Baseline Height (cm) | See 'LABEL' column |  |
| BMI0 | Numeric | Baseline BMI (kg/m2) | See 'LABEL' column |  |
| SEX | Numeric | Gender | 1 (male), 2 (female) |  |