Example dataset 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 | Y1, Y10, Y3, Y8 |  |
| STUDYN | Numeric | Study | 2 (Y10), 1 (Y1), 3 (Y3), 4 (Y8) |  |
| TRTNAME | String | Name actual treatment given to subject | MD IV 15mg/kg,  MD IV 5mg/kg,  MD IV Placebo,  SD IV 1.5 mg/kg,  SD IV 15 mg/kg,  SD IV Placebo,  SD or MD IV Placebo |  |
| TRT | Numeric | TRTNAME | 1 (MD IV 15mg/kg),  2 (MD IV 5mg/kg),  3 (MD IV Placebo),  4 (SD IV 1.5 mg/kg),  5 (SD IV 15 mg/kg),  6 (SD IV Placebo),  7 (SD or MD IV Placebo) |  |
| 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 | String | 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 (Plasma concentration Z),  2 (Efficacy marker),  0 or NA (non-observation records) |  |
| NAME | String | Short name of event | Dose X, Dose Z, Efficacy marker, Plasma concentration Z |  |
| 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 | Dose given in the unit of the 'UNIT' column of this record. 0 for non-dosing records |  |
| ADM | Numeric | Administration input number | 1 (Dose Z), 2 (Dose X),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 additional 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 administration or a non-dosing record |  |
| RATE | Numeric | Rate of infusion | Rate of dose administration for dosing records. 0 indicates a bolus administration 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 |  |
| PROFNR | String | Profile number |  |  |
| PROFTIME | Numeric | Profile time |  |  |
| CENTER | Numeric | Center number | See 'LABEL' column |  |
| SUBJECT | Numeric | Subject number | See 'LABEL' column |  |
| INDNAME | String | Indication name | Healthy volunteers, Indication 1, Indication 2 |  |
| IND | Numeric | Numeric indication flag | 1 (INDNAME=Healthy volunteers),  2 (INDNAME=Indication 1),  3 (INDNAME=Indication 2) |  |
| COMPOUND | String | Name of the studied compound | Z |  |
| STUDYDES | String | Study title, short description | See 'LABEL' column |  |
| PART | Numeric | Part of study as defined per protocol | 1=part 1, A=part A, ... '0' codes for a study with a single part or an undefined value either because information was not available or not needed for the analysis |  |
| EXTENS | Numeric | Extension of the core study | 0=core, 1=extension 1, 2=extension 2, ... '0': codes for core and also for an undefined value either because information was not available or not needed for the analysis |  |
| TRTNAMER | String | Name of randomized treatment | MD IV 15mg/kg, MD IV 5mg/kg, MD IV Placebo, SD IV 1.5 mg/kg, SD IV 15 mg/kg, SD IV Placebo, SD or MD IV Placebo |  |
| TRTR | Numeric | Numeric randomized treatment flag | 1 (TRTNAMER=MD IV 15mg/kg),  2 (TRTNAMER=MD IV 5mg/kg),  3 (TRTNAMER=MD IV Placebo),  4 (TRTNAMER=SD IV 1.5 mg/kg),  5 (TRTNAMER=SD IV 15 mg/kg),  6 (TRTNAMER=SD IV Placebo),  7 (TRTNAMER=SD or MD IV Placebo) |  |
| 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 | Dose, PD, PK |  |
| ULOQ | Numeric | Upper 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 |  |
| COMMENT | String | Comment | Various content - might be 'NA' |  |
| BMI0 | Numeric | Regression parameter BMI0 |  |  |
| AST0 | Numeric | Regression parameter AST0 |  |  |
| FOOD | Numeric | Regression parameter FOOD |  |  |

**Table of Events**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **NAME** | **VALUE** | **VALUETEXT** | **UNIT** | **TYPENAME** | **LLOQ** |
| Dose X | [Numeric] |  | mg | Dose |  |
| Dose Z | [Numeric] |  | mg | Dose |  |
| Plasma concentration Z | [Numeric] |  | ug/mL | PK | 200 |
| Efficacy marker | [Numeric] |  | mm | PD | 50 |
| Age | [Numeric] |  | Years | Demographics |  |
| Gender |  | Male / Female |  | Demographics |  |
| Weight | [Numeric] |  | kg | Demographics |  |
| Health status |  | Unwell / Bad / Good / Excellent |  | Vital Signs |  |