

## Dataset name, description, and location

Name	Description	Location
dataNMLE	Analysis dataset	../Data/01_dataNLME_PK/dataNLME.xpt

## Data specification of dataNMLE

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

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	
COMPOUND	String	Name of the studied compound	HS0815	
STUDY	String	Short study name/number	HS0815-01	
STUDYN	Numeric	Numeric study flag	1 (STUDY=HS0815-01)	
BASE	Numeric	Flag indicating assessments at baseline	0 for non-baseline, 1 for first, 2 for second, ...	
SCREEN	Numeric	Flag indicating assessments at screening	0 for non-screening, 1 for first, 2 for second, ...	
STDTC	String	Start date and time of event		
ENDTC	String	End date and time of event		
TIMEUNIT	String	Unit of all numeric time definitions	'DAYS'	
TIME	Numeric	Actual time relative to first dose	'TIME' values in the unit defined in the 'TIMEUNIT' column	
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, PK	
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	
VALUETXT	String	Text version of value	'NA': if undefined or information not available / not needed for analysis	
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	

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Name	Type	Label	Values	Comments
ROUTE	String	Route of administration	IV. 'NA' for non-dosing 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	
ID	Numeric	Numeric subject ID for modeling software	Numeric subject ID for modeling software	
TIMEPOS	Numeric	Time since first record in subject	'TIMEPOS' values in the unit defined in the 'TIMEUNIT' column	
EVID	Numeric	Event ID	1 for dosing records, 0 for non-dosing records	
MDV	Numeric	Missing dependent variable flag	1 for dosing records and ignored observation records, 0 otherwise	
CENS	Numeric	Censoring flag	1 for observation records below 'LLOQ' if handling in the model via the M3 or M4 method. 0 otherwise	
AMT	Numeric	Dose amount (mg)	Dose given in the unit of the 'UNIT' column of this record. 0 for non-dosing records	
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'.	
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	
ADM	Numeric	Administration input number	1 (HS0815 Dose), 0 or NA (non-dose records)	
YTYPE	Numeric	Observation output number	1 (HS0815 Concentration), 0 or NA (non-observation records)	
TAD	Numeric	Time after last dose	'TAD' values in the unit defined in the 'TIMEUNIT' column	
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	
AGE0	Numeric	Baseline Age (years)	See 'LABEL' column	
HT0	Numeric	Baseline Height (cm)	See 'LABEL' column	
WT0	Numeric	Baseline Weight (kg)	See 'LABEL' column	
ALB0	Numeric	Baseline Albumin (g/dL)	See 'LABEL' column	
CK0	Numeric	Baseline Creatine Kinase (U/L)	See 'LABEL' column	
SEXF	Numeric	Gender	0 (M), 1 (F)	
RACE	Numeric	Race	1 (WHITE), 6 (OTHER)	
TRT	Numeric	Numeric treatment flag	1 (TRTNAME=1 mg/kg), 3 (TRTNAME=3 mg/kg), 10 (TRTNAME=10 mg/kg), 30 (TRTNAME=30 mg/kg)	

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Name	Type	Label	Values	Comments
TRTNAME	String	Name actual treatment given to subject	1 mg/kg, 10 mg/kg, 3 mg/kg, 30 mg/kg	