Data Specification

MetrumRG

2018-01-08 10:16:30

Column	Type	Field	Value
С	character	unit	
		short-name	commented row indicator
		long-name	commented rows
		values	., C
USUBJID	character	unit	
		short-name	USUBJID
		long-name	universal subject identifier
ID	numeric	unit	
		short-name	ID
		long-name	NONMEM ID number
EVID	numeric	unit	
		short-name	EVID
		long-name	event ID indicator
		comment	per NONMEM specifications
MDV	numeric	unit	
		short-name	MDV
		long-name	missing DV indicator
		comment	per NONMEM specifications
SEQ	numeric	unit	•
·		short-name	SEQ
		long-name	record type indicators
		values	1 = concentration, 2 = response, 3 = other
AMT	numeric	unit	mg
		short-name	Amount
		long-name	dose amount
		range	0 to 1000
II	numeric	unit	hours
		short-name	II
		long-name	interdose interval
CMT	numeric	unit	
		short-name	Compartment
		long-name	compartment number
		comment	per NONMEM specifications
		values	1, 2, 3, 4
TAFD	numeric	unit	hours
		short-name	TAFD
		long-name	time after first dose
WT	numeric	unit	kg
		short-name	Weight
		long-name	baseline weight
		range	40 to 100
EGFR	numeric	unit	ml/min/1.73 m2
	1101110110	short-name	eGFR
		long-name	estimated glomerular filtration rate
		range	10 to 300
		141180	10 00 000

Column	Type	Field	Value
STUDY	character	unit	
		short-name	Study
		long-name	study identifier
		values	100 = The first phase 1 study, 202 = The first phase 2 study conducted only at sites 1, 2, 3 when the formulation was still oral liquid only, 303 = The renal impairment study, 203 = The second phase 2 study
SEX	integer	unit	
		short-name	SEX
		values	0 = male, 1 = female
BQL	numeric	unit	
		short-name	below limit of quantification
		long-name	DV value is below the quantitation limit
		values	0 = FALSE, 1 = TRUE
DV	numeric	unit	
		short-name	DV
		long-name	dependent variable
		$\operatorname{comment}$	see SEQ
DV2	numeric	unit	
		short-name	$\mathrm{DV}2$
		long-name	second dependent variable
HAIR	character	unit	
		short-name	HAIR
		long-name	patient hair color
		values	0 = brown, 1 = blonde, 2 = black
CLCR	numeric	unit	$\mathrm{ml/min}$
		short-name	creatinine clearance
		range	40 to 180