CONFIDENTIAL

Analysis data specification

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Description: Example PopPK analysis data set.

Column	Type	Field	Value
C	character	short-name	comment character
		values	. = analysis row, C = commented row
NUM	numeric	short-name	record number
ID	numeric	short-name	subject identifier
SUBJ	character	short-name	subject identifier
TIME	numeric	short-name	time after first dose
		unit	hour
SEQ	numeric	short-name	data type
		values	0 = observation, 1 = dose
CMT	numeric	short-name	compartment number
EVID	numeric	short-name	event ID
		values	0, 1
AMT	numeric	short-name	dose amount
		unit	mg
DV	numeric	short-name	dependent variable
		unit	μg/L
AGE	numeric	short-name	age
		unit	years
WT	numeric	short-name	weight
		unit	kg
CRCL	numeric	short-name	creatinine clearance
		unit	ml/min
ALB	numeric	short-name	albumin
		unit	g/dL
		long-name	serum albumin
BMI	numeric	short-name	BMI
		unit	m2/kg
		long-name	body mass index
AAG	numeric	short-name	alpha-1-acid glycoprotein
		unit	mg/dL
SCR	numeric	short-name	serum creatinine
		unit	mg/dL
AST	numeric	short-name	aspartate aminotransferase
ALT	numeric	short-name	alanine aminotransferase
HT	numeric	short-name	height
		unit	cm
		long-name	Height

Column	Type	Field	Value
CP	numeric	short-name	Child-Pugh score
		values	0 = normal, 1 = Pugh1, 2 = Pugh2, 3 = Pugh3
TAFD	numeric	short-name	time after first dose
		unit	hours
TAD	numeric	short-name	time after dose
		unit	hours
LDOS	numeric	short-name	last dose amount
		unit	mg
MDV	numeric	short-name	MDV
		values	0, 1
		long-name	missing DV indicator
		comment	per NONMEM specifications
BLQ	numeric	short-name	below limit of quantification
		values	1, 0
PHASE	numeric	short-name	study phase indicator
		values	1
STUDY	numeric	short-name	study number
		values	1 = SAD, 2 = MAD, 3 = Renal, 4 = Hepatic
RF	character	short-name	renal function stage
		values	norm = Normal, mild = Mild, mod = Moderate, sev = Severe

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Description: Population PKPD analysis data set

Column	Type	Field	Value
C	character	short-name	C
		values	., C
		long-name	commented rows
MDV	numeric	short-name	MDV
		long-name	missing DV indicator
		comment	per NONMEM specifications
SEQ	numeric	short-name	SEQ
		values	1 = concentration, 2 = response, 3 = other
		long-name	record type indicators
AMT	numeric	short-name	AMT
		unit	mg
		range	0 to 1000
		long-name	dose amount
II	numeric	short-name	II
		unit	hours
		long-name	interdose interval
CMT	numeric	short-name	Compartment
		values	1, 2, 3, 4
		long-name	compartment number
		comment	per NONMEM specifications

Column	Type	Field	Value
TAFD	numeric	short-name	TAFD
		unit	hours
		long-name	time after first dose
WT	numeric	short-name	Weight
		unit	kg
		range	40 to 100
		long-name	baseline weight
EGFR	numeric	short-name	eGFR
		unit	ml/min/1.73 m2
		range	10 to 300
		long-name	estimated glomerular filtration rate
SEX	numeric	short-name	SEX
		values	0 = male, 1 = female