CONFIDENTIAL

Analysis data specification

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1 Datasets

Description	Location
Example PopPK analysis data set.	analysis1.xpt
Population PKPD analysis data set	DEM104101F_PKPD.xpt

1.1 Example PopPK analysis data set. (`analysis1.xpt`)

VARIABLE	LABEL	TYPE	CODES
C	comment character	character	. = analysis row, C = commented row
NUM	record number	numeric	
ID	subject identifier	numeric	
SUBJ	subject identifier	character	
TIME	time after first dose (unit: hour)	numeric	
SEQ	data type	numeric	0 = observation, 1 = dose
CMT	compartment number	numeric	
EVID	event ID	numeric	values: 0, 1
AMT	dose amount (unit: mg)	numeric	
DV	dependent variable (unit: μg/L)	numeric	
AGE	age (unit: years)	numeric	
WT	weight (unit: kg)	numeric	
CRCL	creatinine clearance (unit: ml/min)	numeric	
ALB	serum albumin (unit: g/dL)	numeric	
BMI	body mass index (unit: m2/kg)	numeric	
AAG	alpha-1-acid glycoprotein (unit: mg/dL)	numeric	
SCR	serum creatinine (unit: mg/dL)	numeric	
AST	aspartate aminotransferase	numeric	
ALT	alanine aminotransferase	numeric	
HT	Height (unit: cm)	numeric	
CP	Child-Pugh score	numeric	0 = normal, 1 = Pugh1, 2 = Pugh2, 3 = Pugh3
TAFD	time after first dose (unit: hours)	numeric	
TAD	time after dose (unit: hours)	numeric	
LDOS	last dose amount (unit: mg)	numeric	
MDV	missing DV indicator	numeric	values: 0, 1
BLQ	below limit of quantification	numeric	values: 1, 0
PHASE	study phase indicator	numeric	values: 1
STUDY	study number	numeric	1 = SAD, 2 = MAD, 3 = Renal, 4 = Hepatic
RF	renal function stage	character	norm = Normal, mild = Mild, mod = Moderate, sev = Severe

1.2 Population PKPD analysis data set (`DEM104101F_PKPD.xpt`)

VARIABLE	LABEL	TYPE	CODES
C	commented rows	character	values: ., C
MDV	missing DV indicator	numeric	
SEQ	record type indicators	numeric	1 = concentration, 2 = response, 3 = other
AMT	dose amount (unit: mg)	numeric	
II	interdose interval (unit: hours)	numeric	
CMT	compartment number	numeric	values: 1, 2, 3, 4
TAFD	time after first dose (unit: hours)	numeric	
WT	baseline weight (unit: kg)	numeric	
EGFR	estimated glomerular filtration rate (unit: ml/min/1.73 m2)	numeric	
SEX	SEX	numeric	0 = male, 1 = female