CONFIDENTIAL

Analysis data specification

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1 Datasets

Description	Location
[data set description]	spec.xpt
Population PKPD analysis data set	DEM104101F_PKPD.xpt

1.1 [data set description] (`spec.xpt`)

VARIABLE	LABEL	TYPE	CODES
C	commented rows	character	values: ., C
USUBJID	universal subject identifier	character	
ID	NONMEM ID number	numeric	
EVID	event ID indicator	numeric	
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/1.73m2)	numeric	
STUDY	study identifier	character	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	SEX	numeric	0 = male, 1 = female
BQL	DV value is below the quantitation limit	numeric	0 = FALSE, 1 = TRUE
DV	dependent variable (unit: ng/mL)	numeric	
DV2	second dependent variable	numeric	
HAIR	patient hair color	character	0 = brown, 1 = blonde, 2 = black
CLCR	creatinine clearance (unit: ml/min)	numeric	
ALB	adjusted albumin (unit: g/dL)	numeric	

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

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