Data Definitions

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1 Datasets

Description	Location
Example PopPK analysis data set	analysis2.xpt

1.1 Example PopPK analysis data set (`analysis2.xpt`)

VARIABLE	LABEL	TYPE	CODES
C	comment character	character	C = comment, . = non-comment
NUM	record number	numeric	
ID	subject identifier	numeric	
TIME	time after first dose (unit: hour)	numeric	
SEQ	data type	numeric	0 = observation, 1 = dose
CMT	compartment number	numeric	
EVID	event ID	numeric	0 = observation, 1 = dose
AMT	dose amount (unit: mg)	numeric	
DV	dependent variable	numeric	
AGE	age (unit: years)	numeric	
WT	weight (unit: kg)	numeric	
HT	height (unit: cm)	numeric	
CRCL	creatinine clearance (unit: ml/min)	numeric	
ALB	albumin (unit: g/dL)	numeric	
BMI	body mass index (unit: m2/kg)	numeric	
SEX	SEX	numeric	0 = male, 1 = female
AAG	alpha-1-acid glycoprotein (unit: mg/dL)	numeric	
SCR	serum creatinine (unit: mg/dL)	numeric	
AST	aspartate aminotransferase	numeric	
ALT	alanine aminotransferase	numeric	
CP	Child-Pugh score	numeric	0 = normal, 1 = score=1, 2 = score=2, 3 = score=3
TAFD	time after first dose (unit: hour)	numeric	
TAD	time after dose (unit: hour)	numeric	
LDOS	last dose amount (unit: mg)	numeric	
MDV	missing DV indicator	numeric	0 = non-missing, 1 = missing
BLQ	below limit of quantification	numeric	1 = above QL, 0 = below Q
PHASE	study phase indicator	numeric	values: 1
STUDYN	study number	numeric	values: 1, 2, 3, 4
DOSE	nominal dose amount	numeric	values: 5, 10, 25, 50, 75, 100, 150, 200

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VARIABLE	LABEL	TYPE	CODES
SUBJ	subject identifier	character	
USUBJID	unique subject identifier	character	
STUDY	study name	character	values: 101-DEMO-001, 101-DEMO-002, 201-DEMO-003, 201-DEMO-004
ACTARM	treatment arm	character	values: DEMO 5 mg, DEMO 10 mg, DEMO 10 mg qd x7, DEMO 25 mg, DEMO 25 mg qd x7, DEMO 50 mg qd x7, DEMO 75 mg qd x7, DEMO 100 mg, DEMO 100 mg qd x7, DEMO 150 mg, DEMO 200 mg
RF	renal function stage	character	norm = normal, mild, mod = moderate, sev = severe