



CONFIDENTIAL

# Analysis data specification

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**Author:**

Michelle Johnson  
Metrum Research Group  
Tunxis Road, Suite 112  
Tariffville, CT 06081

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## 1 analysis1

**Description:** Example PopPK analysis data set.

Column	Type	Field	Value
C	character	short-name values	comment character . = 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 unit	TIME hour
SEQ	numeric	short-name values	SEQ 0 = observation, 1 = dose
CMT	numeric	short-name	compartment number
EVID	numeric	short-name values	event ID 0, 1
AMT	numeric	short-name unit	dose amount mg
DV	numeric	short-name unit	dependent variable $\mu\text{g/L}$
AGE	numeric	short-name unit	age years
WT	numeric	short-name unit	weight kg
CRCL	numeric	short-name unit	CRCL ml/min
ALB	numeric	short-name unit long-name	albumin g/dL serum albumin
BMI	numeric	short-name unit long-name	BMI m <sup>2</sup> /kg body mass index
AAG	numeric	short-name unit	alpha-1-acid glycoprotein mg/dL
SCR	numeric	short-name unit	serum creatinine mg/dL
AST	numeric	short-name	aspartate aminotransferase
ALT	numeric	short-name	alanine aminotransferase
HT	numeric	short-name unit long-name	height cm Height

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

## 2 DEM104101F\_PKPD

**Description:** Population PKPD analysis data set

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

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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