CONFIDENTIAL

Analysis data specification

2019-01-15

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

Contents

1 spec

Description: an example data set

Column	Type	Field	Value
C	character	short-name	commented row indicator
		values	., C
		long-name	commented rows
USUBJID	character	short-name	USUBJID
		long-name	universal subject identifier
ID	numeric	short-name	ID
		long-name	NONMEM ID number
EVID	numeric	short-name	event ID
		long-name	event ID indicator
		comment	per NONMEM specifications
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	amount
		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
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/1.73m2
		range	10 to 300

Column	Type	Field	Value
		long-name	estimated glomerular filtration rate
STUDY	character	short-name	Study
		values	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
		long-name	study identifier
SEX	numeric	short-name	SEX
		values	0 = male, 1 = female
BQL	numeric	short-name	below limit of quantification
		values	0 = FALSE, 1 = TRUE
		long-name	DV value is below the quantitation limit
DV	numeric	short-name	DV
		unit	ng/mL
		long-name	dependent variable
		comment	see SEQ
DV2	numeric	short-name	DV2
		long-name	second dependent variable
HAIR	character	short-name	HAIR
		values	0 = brown, 1 = blonde, 2 = black
		long-name	patient hair color
CLCR	numeric	short-name	creatinine clearance
		unit	ml/min
		range	40 to 180
ALB	numeric	short-name	adjusted albumin
		unit	g/dL
		range	1 to 5
		comment	in the lookup document as ALB2

2 DEM104101F_PKPD

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

Column	Type	Field	Value
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
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