

Data Set Definitions

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Contents

1	DEM104101F_PK	1
2	DEM104101F_PKPD	1
3	DEM104101F_AE	2

1 DEM104101F_PK

Description: Population PK analysis data set

Column	Type	Field	Value
C	character	short-name values long-name	C . = not a comment, C = comment commented rows
USUBJID	character	short-name long-name	USUBJID universal subject identifier
ID	character	short-name long-name	ID NONMEM ID number
EVID	numeric	short-name long-name comment	EVID event ID indicator per NONMEM specifications
WT	numeric	short-name range	WT 2 to 4

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

Continued on next page

Column	Type	Field	Value
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
TAFD	numeric	short-name unit long-name	TAFD hours time after first dose
WT	numeric	short-name unit range long-name	Weight kg 40 to 100 baseline weight
EGFR	numeric	short-name unit range long-name	eGFR ml/min/1.73 m2 10 to 300 estimated glomerular filtration rate
SEX	numeric	short-name values	SEX 0 = male, 1 = female

3 DEM104101F_AE

Description: AE 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	Compartment 1, 2, 3, 4

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Column	Type	Field	Value
		long-name comment	compartment number per NONMEM specifications
TAFD	numeric	short-name unit long-name	TAFD hours time after first dose
WT	numeric	short-name unit range long-name	Weight kg 40 to 100 baseline weight
EGFR	numeric	short-name unit range long-name	eGFR ml/min/1.73 m2 10 to 300 estimated glomerular filtration rate