



CONFIDENTIAL

## Data Definitions

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## 1 Datasets

Description	Location
Population PK analysis data set	DEM104101F_PK.xpt
Population PK/PD analysis data set	DEM104101F_PKPD.xpt
AE analysis data set	DEM104101F_AE.xpt

### 1.1 Population PK analysis data set (DEM104101F\_PK.xpt)

VARIABLE	LABEL	TYPE	CODES
C	commented rows	character	. = not a comment, C = comment
USUBJID	universal subject identifier	character	
ID	NONMEM ID number	character	
EVID	event ID indicator	numeric	
WT	WT	numeric	

### 1.2 Population PK/PD analysis data set (DEM104101F\_PKPD.xpt)

VARIABLE	LABEL	TYPE	CODES
C	commented rows	character	values: ., C
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/1.73 m2)	numeric	
SEX	SEX	numeric	0 = male, 1 = female

### 1.3 AE analysis data set (DEM104101F\_AE.xpt)

VARIABLE	LABEL	TYPE	CODES
C	commented rows	character	values: ., C
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

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VARIABLE	LABEL	TYPE	CODES
TAFD	time after first dose (unit: hours)	numeric	
WT	baseline weight (unit: kg)	numeric	
EGFR	estimated glomerular filtration rate (unit: ml/min/1.73 m2)	numeric	