Population PK Dataset (mk7655-poppk-20180503-v2.xpt)

Variable	Label	Code List	Comments
C	Comment	A='missing datetime' B='missing conc.' C='predose non 0 conc' D='stabilizer issue' E='dosing error' F='pre-dialysis, PN=5,period 2' G='unreasonably hig concentrations' H='Discont. trt due to AE, excluded' I='DV(T>0.5) > DV(T=0.5) for PN=3,4' J=Outlier	
NROW	Record number	1 to N	Each row should be sequentially numbered from 1 to N[where N is the total number of rows in the dataset]
PN	Protocol number (study)	1, 2, 5, 3, 4, 12, 7, 9, 13, 19	
PID	Allocation number	For PN003, last 7 digits of USUBJID for PN007, last 6 digits of USUBJID for PN009, last 6 digits of USUBJID for PN012, last 6 digits of USUBJID for PN013, PN020 SUBJID for PN019, last 7 digits of USUBJID	

Variable	Label	Code List	Comments
ID	Unique subject ID	ID=PN*1000 + PID ; For P004 ID=7000+ 1(to N) where N is the number of subjects in P004 For P003 ID=30000000+last 7 digits from USUBJID For P012 ID=12000000+last 6 digits from USUBJID For P007 ID=7000000+last 6 digits from USUBJID For P009 ID=9000000+last 6 digits from USUBJID For P013 ID=13000000+SUBJID For P019 ID=19000000+last 7 digits from USUBJID; P020= 20*(10^6)+AN	
PART	Part	For PN 001, number from "Part" column (1,2,3,4) ; refer appendix1. For PN 002, 005, 003, 004,007,009, 012,019 and 013 and 020 hardcode "1" for all	
PANL	Panel	For PN 001, 002, 005 & 012: Letter only from "Panel" column; '1'=A, '2'=B, etc. For PN 003, 004, 007, 009, 019 & 013 : treatment group per protocol (1,2,3)	
PERD	Period		For PN 003 &004 : some subjects crossed over to panel 1 from panels 2 or 3 after day 4; record these switches as PERD=2, period information avaibale in P012, P019 source data
GRP	Unique dose combination group		For PN001 & PN009: refer appendix of PRS. For PN002 : GRP=10. For PN005 : GRP =15. For PN 003, 004, 012 & 019 : GRP = "11" for PANL=1, "10" for PANL=2 and "8" for PANL=3 For PN007 GRP=11 PN013: if PANL 1 & 3 then GRP=11, if PANL=2 then GRP=8
SDMD	Single dose or multiple dose		1'=SD (PN 001 PART 1, PN 002 , PN 005, PN009 & PN019); '2'=MD (PN 001 PARTS 2-4, PN003 PN007, PN004 & PN013). P012:According to ELEMENT variable
COAD	Co-administration of drugs		"1' = YES, '0' = NO (YES meaning MK-7655 and IPM are coadministered) ; If GRP = 1- 8 COAD=0 else COAD =1 PN013:if PANL=1 & 3 then COAD=1, if PANL=2 then COAD=0; PN019:COAD=1
DRUG	Drug compound (MK-7655 or Imipenem)	1'=Imipenem, '2'=MK7655	

Variable	Label	Code List	Comments
DOSE	Dose (mg)		Dose in mg; See Appendix1 of PRS for chart of doses by GRP/PN/PART/PANEL/PERD ; should be entered for all rows for a subject, for EVID=4 and EVID=0 Note: for PN004 actual dose may be different from planned dose listed in appendix1. Record actual dose in such cases. For PN003, dose values are captured from the EX.EXDOSTOT variable. The derivation of the amounts in this variable is based on - (prepared dose(mg)*Volume taken)/Volume prepared
DAY	Day number		actual day of PK sample collection ; define day by TIME, e.g. day = 1 if 0 <= TIME < 24, day = 2 if 24 <= TIME < 48 … etc ; If actual day < 0 enter "-1"
RNTM	Relative nominal time (hr)		planned time for dosing or PK sample collection relative to 0 hour for that particular DAY of observation
TIME	Actual Time since first dose (hr)		actual time since first dose in same period ; For PN001: If same subject has received 2 or more dose levels / GRP/ different periods, the TIME is reset to 0h at EVID=4 for each period (/GRP/dose level) for that subject
TSLD	Actual time since last dose		difference between the actual time of the PK sample and the actual start of the infusion for the dose immediately preceding the PK collection
CONC	Plasma concentration (nmol/L)		For PN001, 002 and 005 : CONC=IPM_C3 or MK_C3 for observation records, round to 1 decimal place; For PN004 : Conc= "Conc-Accepted (µg/mL)" for observation records. For records with duplicate ID & DRUG & EVID & TIME but with different CONC : verify with source data that DAY & TIME is correctly captured since it may be samples on different visits (check VISITNUM in BS file). Convert to nmol/L using CONC= conc in ug/ml * 1e6/MW ; round to 1 decimal place ; MW=299.351 for IPM and MW= 348.38 for MK-7655 ; CONC= "." for dose records
MDV	Missing dependent variable	If CONC=. or 0 then MDV=1 ; else MDV=0	
EVID	Event ID		EVID = 4 for Dose records, EVID = 0 for observation records ; order records by ID, DRUG, COAD, DOSE, TIME, descending EVID (= 4 first, = 0 second if TIME is identical for two records) . For PN001, single dose arms for each subject, EVID=4 only for the 1st dosing event. Following dosing events should have EVID=1. For PN001, multiple dose arms, for each subject, EVID=4 only for the 1st dosing event. Following dosing events should have EVID=1. PN013: EVID=1 for all dosing records, except for the first instance when DRUG=2 then EVID=4

Variable	Label	Code List	Comments
AMT	Dose amount (nmol)		create Dosing records : If SDMD=1, single row inserted before the TIME=0 for each subject, for each DRUG, for each PERD ; If SDMD=2, capture each dosing record as is at actual time of dosing. AMT=(DOSE*1e6 / MW) for dose records; round to 1 decimal place; AMT=0 for observation records. MW for Imipenem: 299.351 g/mol, and for Relebactam: 348.38 g/mol.
RATE	Infusion rate (nmol/hr)		RATE = AMT / actual infusion duration ; round to 1 decimal place. Infusion duration is expected to be 0.5 h but there may be deviations
ADDL	Number of additional doses		For dose records: ADDL=0 ; For observation records: ADDL= "."
II	Interdose interval (hr)	If ADDL=0, II=0 ; Else II = "."	
CMT	Compartment		Hardcode CMT=1 for all
CRCL	Creatinine clearance (mL/min)		CrCl (mL/min) = ((140 – AGE) * WT{kg}) / (72 * SECR {mg/dL}). For female subjects (MALE=0) multiply the result by 0.85 ; round to 1 decimal place. If subjects are pediatric subjects (PN020), the CrCL = kL/SECR, where L is height in centimeters, SECR is Serum Creatinine is mg/dL and k is 0.45 if AGE < 1 yr, 0.55 for children and adolescent girls (AGE >12 and < 18 yrs), 0.7 for adolescent boys (AGE >12 and < 18 yrs)
RENL	Categorical CRCL bin		CRCL >=90 then "1"; CRCL >=60 to <90 then "2" ; CRCL >=30 to <60 then "3" ; CRCL >=15 to <30 then "4". If CRCL < 15 then "."
WT	Body Weight (kg)		round to 1 decimal place
WTBN	Categorical body weight bin		WT >=70 then "1" ; WT >=60 to <70 then "2" ; WT >=50 to <60 then "3" ; WT>=40 to <50 then "4" ; WT >=30 to <40 then "5". If WT < 30 then "."
AGE	Age (yr.)		round to integer
MALE	Gender	0 if Female or 1 if Male.	
HLTH	Healthy volunteer or patient	1 for PN001, PN002, PN005, PN007, PN009, PN012 & PN019; 0 for PN004, PN003 & PN013	
HT	Height (cm)		round to integer
RACE	Race	1 if White, 2 if Black, 3 if Asian and 4 if any other	
SECR	Serum creatinine (mg/dL)		time varying, round to 2 decimal places
RICH	Rich profiles	if PN 003, 004, 007 & 019 then 1 else 0	

Variable	Label	Code List	Comments
INFC	Type of infections	0-HV 1-cIAI 2-cUTI 3-HABP/VABP	
TREAT	Treatment identifier		Assigned to PK observations depending on the single or combination treatment: TREAT=1 if 'MK-7655A Alone'; TREAT=2 if 'MK-7655A + Probenecid'. Only for PN019 study