

## Datasets for Pharmacokinetics of Clindamycin and Trimethoprim-Sulfamethoxazole in Infants and Children

Dataset	Description of dataset
AE_SAE	Adverse event dataset
CLAB	Chemistry lab dataset
CM	Concomitant medication dataset
DES_CODELIST	Raw codelist definitions dataset
DM	Demographics dataset
DOSE	Study drug dosing dataset
DS	Disposition dataset
HLAB	Hematology lab dataset
IE	Inclusion/exclusion criteria dataset
MH	Medical history dataset
OPPK	Opportunistic PK draw dataset
PE	Physical exam dataset
PKU	Urine PK dataset
PRVDRG	Previous study drug dosing dataset
PT	Pregnancy test dataset
SOCD	Standard of care dataset
SV	Date of visit dataset
DES_FORMATS	Codelists, combined codelists, and system codelists dataset
CLINDAMYCIN_AAG	PBPK-R01 Clindamycin Alpha-1-acid Glycoprotein (AAG) Sample Analysis Results
CLINDAMYCIN_PLASMA_FINAL	PBPK-R01 Clindamycin Plasma Sample Analysis Results
CLINDAMYCIN_PLASMA_INTERIM	PBPK-R01 Clindamycin Plasma Interim Results
CLINDAMYCIN_URINE	PBPK-R01 Clindamycin Urine Sample Analysis Results
TMP_SMX_PLASMA	PBPK-R01 Trimethoprim-Sulfamethoxazole Plasma Sample Analysis Results
TMP_SMX_URINE	PBPK-R01 Trimethoprim-Sulfamethoxazole Urine Sample Analysis Results

## AE\_SAE

Variable	Type	Label	Format	Redacted
DEIDNUM	Num	Deidentified subject id		
AEACN	Num	Action taken regarding study drug	ACTION.	
AEACN_DEC	Char	Action taken regarding study drug (displ		
AEDIMTD	Num	If study drug was discontinued, interrup	YNNA.	
AEDIMTD_DEC	Char	If study drug was discontinued, interrup		
AEDINRD	Num	If study drug was interrupted, is this a	YNNA.	
AEDINRD_DEC	Char	If study drug was interrupted, is this a		
AEDIS	Num	If study drug was discontinued, is this	YNNA.	
AEDIS_DEC	Char	If study drug was discontinued, is this		
AEENDT	Num	StudyDay of AE stop date		
AEENDTM	Char	AE stop time	\$EMPTYSTATE.	
AEENDTM_DEC	Char	AE stop time (display value)		
AEONGO	Num	Ongoing	ONGOING.	
AEONGO_DEC	Char	Ongoing (display value)		
AEOUT	Num	AE Outcome	OUTCOME.	
AEOUT_DEC	Char	AE Outcome (display value)		
AERAPR	Num	If study drug was restarted (Rechallenge	YNNA.	
AERAPR_DEC	Char	If study drug was restarted (Rechallenge		
AEREL	Num	Relationship of AE with study drug	RELATIONSHIP.	
AERELST	Char	Rationale for relationship with study dr		
AEREL_DEC	Char	Relationship of AE with study drug (disp		
AESCONG	Char	Congenital anomaly or birth defect		
AESDISAB	Char	Persistent or significant disability/inc		
AESDTH	Char	Death		
AESER	Num	Was this event serious? (If yes, check a	YESNO.	
AESER_DEC	Char	Was this event serious? (If yes, check a		
AESEV	Num	AE severity	SEVER.	
AESEV_DEC	Char	AE severity (display value)		
AESHOSP	Char	Require inpatient hospitalization or pro		
AESLIFE	Char	Life-threatening		
AESMIE	Char	Important medical event		
AESPID	Char	AE Number		REDACT
AESTDT	Num	StudyDay of AE onset date		
AESTTM	Char	AE onset time	\$EMPTYSTATE.	
AESTTM_DEC	Char	AE onset time (display value)		
AETERM	Char	AE Term		

## AE\_SAE

Variable	Type	Label	Format	Redacted
ALTNONE	Char	None (Only applicable if study drug rela		
CONCOMED	Char	Concomitant medication		
CONCOMIL	Char	Concomitant illness		
CONSPEC	Char	Specify		
DATALMBY	Char	Data Last Modified By		REDACT
DATALMDT	Num	StudyDay of Data Last Modified Date		
DELETED	Char	Marked Deleted		
ILLSPEC	Char	Specify		
MMMEDDRA	Char	MedDRA Preferred Term		
NAREND	Num	Is Narrative entry completed?	YESNOSAE.	
NAREND_DEC	Char	Is Narrative entry completed? (display v		
NARRNOT	Char	SAE Narrative page is not needed		
NARSYMP	Char	SAE Narrative		
NOAE	Char	No Adverse Events occurred		
OTHCAUS	Char	Other known or suspected cause		
OTHSPEC	Char	Specify		
PAGEID	Num	Page Id		
PAGELMBY	Char	Page Last Modified By		REDACT
PAGELMDT	Num	StudyDay of Page Last Modified Date		
PAGENAME	Char	Page Name		
PAGESEQ	Num	Page Seq		
PISIG	Char	I verify that this SAE report form accur		REDACT
PRIMDIS	Char	Primary disease under study		
SAECMID	Num	Was the subject on any concomitant medic	YESNO.	
SAECMID_DEC	Char	Was the subject on any concomitant medic		
SAELABYN	Num	Were there any relevant laboratory or di	YESNO.	
SAELABYN_DEC	Char	Were there any relevant laboratory or di		
SITENUM	Char	Site Number		REDACT
STATUSID	Num	Page Status Id	DESPGST.	
STATUSID_DEC	Char	Page Status Id (display value)		
STPRSPEC	Char	Specify		
STUDPROC	Char	Study procedure		
VISITID	Num	Visit Id		
VISITSEQ	Num	Visit Seq		
VISNAME	Char	Visit Name		

## CLAB

Variable	Type	Label	Format	Redacted
DEIDNUM	Num	Deidentified subject id		
ALBDT	Num	StudyDay of Albumin date		
ALBND	Num	Albumin done	YESNO.	
ALBND_DEC	Char	Albumin done (display value)		
ALBSM	Char	Albumin same date and time		
ALBTM	Num	Albumin time	TIME5.	
ALBUN	Num	Albumin unit	ALBU.	
ALBUN_DEC	Char	Albumin unit (display value)		
ALBVA	Num	Albumin value		
ALPDT	Num	StudyDay of Alkaline Phosphatase date		
ALPND	Num	Alkaline Phosphatase done	YESNO.	
ALPND_DEC	Char	Alkaline Phosphatase done (display value)		
ALPRSLT	Num	Alkaline Phosphatase Results	NORMALCLINABNORM AL_LIB.	
ALPRSLT_DEC	Char	Alkaline Phosphatase Results (display va		
ALPSM	Char	Alkaline Phosphatase same date and time		
ALPTM	Num	Alkaline Phosphatase time	TIME5.	
ALPUN	Num	Alkaline Phosphatase unit	ALKPU.	
ALPUN_DEC	Char	Alkaline Phosphatase unit (display value)		
ALPVA	Num	Alkaline Phosphatase value		
ALRSLT	Num	Albumin Results	NORMALCLINABNORM AL_LIB.	
ALRSLT_DEC	Char	Albumin Results (display value)		
ALTDT	Num	StudyDay of ALT date		
ALTND	Num	ALT done	YESNO.	
ALTND_DEC	Char	ALT done (display value)		
ALTRSLT	Num	ALT Results	NORMALCLINABNORM AL_LIB.	
ALTRSLT_DEC	Char	ALT Results (display value)		
ALTSM	Char	ALT same date and time		
ALTTM	Num	ALT time	TIME5.	
ALTUN	Num	ALT unit	ALTU.	
ALTUN_DEC	Char	ALT unit (display value)		
ALTVA	Num	ALT value		
ASTDT	Num	StudyDay of AST date		
ASTND	Num	AST done	YESNO.	
ASTND_DEC	Char	AST done (display value)		

## CLAB

Variable	Type	Label	Format	Redacted
ASTRSLT	Num	AST Results	NORMALCLINABNORMAL_LIB.	
ASTRSLT_DEC	Char	AST Results (display value)		
ASTSM	Char	AST same date and time		
ASTTM	Num	AST time	TIME5.	
ASTUN	Num	AST unit	ASTU.	
ASTUN_DEC	Char	AST unit (display value)		
ASTVA	Num	AST value		
BUNDT	Num	StudyDay of BUN date		
BUNND	Num	BUN done	YESNO.	
BUNND_DEC	Char	BUN done (display value)		
BUNRSLT	Num	BUN Results	NORMALCLINABNORMAL_LIB.	
BUNRSLT_DEC	Char	BUN Results (display value)		
BUNSM	Char	BUN same date and time		
BUNTM	Num	BUN time	TIME5.	
BUNUNIT	Num	BUN unit	BUNU.	
BUNUNIT_DEC	Char	BUN unit (display value)		
BUNVAL	Num	BUN value		
CADT	Num	StudyDay of Calcium date		
CAND	Num	Calcium done	YESNO.	
CAND_DEC	Char	Calcium done (display value)		
CARSLT	Num	Calcium Results	NORMALCLINABNORMAL_LIB.	
CARSLT_DEC	Char	Calcium Results (display value)		
CASM	Char	Calcium same date and time		
CATM	Num	Calcium time	TIME5.	
CAUNT	Num	Calcium unit	CALCU.	
CAUNT_DEC	Char	Calcium unit (display value)		
CAVAL	Num	Calcium value		
CRTDT	Num	StudyDay of Creatinine date		
CRTND	Num	Creatinine done	YESNO.	
CRTND_DEC	Char	Creatinine done (display value)		
CRTRSLT	Num	Creatinine Results	NORMALCLINABNORMAL_LIB.	
CRTRSLT_DEC	Char	Creatinine Results (display value)		
CRTSM	Char	Creatinine same date and time		
CRTTM	Num	Creatinine time	TIME5.	

## CLAB

Variable	Type	Label	Format	Redacted
CRTUNIT	Num	Creatinine unit	CREATU.	
CRTUNIT_DEC	Char	Creatinine unit (display value)		
CRTVAL	Num	Creatinine value		
DATALMBY	Char	Data Last Modified By		REDACT
DATALMDT	Num	StudyDay of Data Last Modified Date		
DBILDT	Num	StudyDay of Direct Bilirubin date		
DBILND	Num	Direct Bilirubin done	YESNO.	
DBILND_DEC	Char	Direct Bilirubin done (display value)		
DBILSM	Char	Direct Bilirubin same date and time		
DBILTM	Num	Direct Bilirubin time	TIME5.	
DBILUN	Num	Direct Bilirubin unit	TOTBILU.	
DBILUN_DEC	Char	Direct Bilirubin unit (display value)		
DBILVA	Num	Direct Bilirubin value		
DBRSLT	Num	Direct Bilirubin Results	NORMALCLINABNORMAL_LIB.	
DBRSLT_DEC	Char	Direct Bilirubin Results (display value)		
DELETED	Char	Marked Deleted		
LABDT	Num	StudyDay of Lab date		
LABNAME	Char	Lab Name		REDACT
LABTM	Num	Lab time	TIME5.	
NADT	Num	StudyDay of Sodium date		
NAND	Num	Sodium done	YESNO.	
NAND_DEC	Char	Sodium done (display value)		
NARSLT	Num	Sodium Results	NORMALCLINABNORMAL_LIB.	
NARSLT_DEC	Char	Sodium Results (display value)		
NASM	Char	Sodium same date and time		
NATM	Num	Sodium time	TIME5.	
NAUNIT	Num	Sodium unit	SODU.	
NAUNIT_DEC	Char	Sodium unit (display value)		
NAVAL	Num	Sodium value		
PAGEID	Num	Page Id		
PAGELMBY	Char	Page Last Modified By		REDACT
PAGELMDT	Num	StudyDay of Page Last Modified Date		
PAGENAME	Char	Page Name		
PAGESEQ	Num	Page Seq		
POTDT	Num	StudyDay of Potassium date		

## CLAB

Variable	Type	Label	Format	Redacted
POTND	Num	Potassium done	YESNO.	
POTND_DEC	Char	Potassium done (display value)		
POTRSLT	Num	Potassium Results	NORMALCLINABNORMAL_LIB.	
POTRSLT_DEC	Char	Potassium Results (display value)		
POTSM	Char	Potassium same date and time		
POTTM	Num	Potassium time	TIME5.	
POTUN	Num	Potassium unit	POTU.	
POTUN_DEC	Char	Potassium unit (display value)		
POTVA	Num	Potassium value		
SITENUM	Char	Site Number		REDACT
STATUSID	Num	Page Status Id	DESPGST.	
STATUSID_DEC	Char	Page Status Id (display value)		
TBILDT	Num	StudyDay of Total Bilirubin date		
TBILND	Num	Total Bilirubin done	YESNO.	
TBILND_DEC	Char	Total Bilirubin done (display value)		
TBILSM	Char	Total Bilirubin same date and time		
TBILTM	Num	Total Bilirubin time	TIME5.	
TBILUN	Num	Total Bilirubin unit	TOTBILU.	
TBILUN_DEC	Char	Total Bilirubin unit (display value)		
TBILVA	Num	Total Bilirubin value		
TBRSLT	Num	Total Bilirubin Results	NORMALCLINABNORMAL_LIB.	
TBRSLT_DEC	Char	Total Bilirubin Results (display value)		
VISITID	Num	Visit Id		
VISITSEQ	Num	Visit Seq		
VISNAME	Char	Visit Name		

## CM

Variable	Type	Label	Format	Redacted
DEIDNUM	Num	Deidentified subject id		
CMDOSU	Num	Dose Unit	UNIT.	
CMDOSU_DEC	Char	Dose Unit (display value)		
CMENDT	Num	StudyDay of Stop Date		
CMINDC	Char	Indication		
CMONG	Num	Ongoing	ONGOING.	
CMONG_DEC	Char	Ongoing (display value)		
CMSPID	Char	Concomitant Medication Number		
CMSTDT	Num	StudyDay of Start Date		
CMTDDOSE	Num	Total daily dose		
CMTRT	Char	Medication Name		
DATALMBY	Char	Data Last Modified By		REDACT
DATALMDT	Num	StudyDay of Data Last Modified Date		
DELETED	Char	Marked Deleted		
PAGEID	Num	Page Id		
PAGELMBY	Char	Page Last Modified By		REDACT
PAGELMDT	Num	StudyDay of Page Last Modified Date		
PAGENAME	Char	Page Name		
PAGESEQ	Num	Page Seq		
SITENUM	Char	Site Number		REDACT
STATUSID	Num	Page Status Id	DESPGST.	
STATUSID_DEC	Char	Page Status Id (display value)		
VISITID	Num	Visit Id		
VISITSEQ	Num	Visit Seq		
VISNAME	Char	Visit Name		



## DES\_CODELIST

<b>Variable</b>	<b>Type</b>	<b>Label</b>	<b>Format</b>	<b>Redacted</b>
DEIDNUM	Num	Deidentified subject id		
CODENAME	Char	Coded value		
DESCRIPTION	Char	Codelist description		
DISPLAYNAME	Char	Displayed value		
DORDER	Num	Display order within codelist		
HIDDEN	Char	Indicates that a value is hidden		
NAME	Char	Codelist name		

## DM

Variable	Type	Label	Format	Redacted
DEIDNUM	Num	Deidentified subject id		
ASIAN	Char	Asian		
BLACK	Char	Black or African American		
BIRTHDT	Num	StudyDay of Date of Birth		
BIRTHWT	Num	Body weight at birth in kg	EMPTYSTATE.	
BIRTHWT_DEC	Char	Body weight at birth in kg (display valu		
CHDPOT	Num	Is the patient of child-bearing potentia	YESNO.	
CHDPOT_DEC	Char	Is the patient of child-bearing potentia		
DATALMBY	Char	Data Last Modified By		REDACT
DATALMDT	Num	StudyDay of Data Last Modified Date		
DELETED	Char	Marked Deleted		
ETHNIC	Num	Ethnicity	ETHNIC.	
ETHNIC_DEC	Char	Ethnicity (display value)		
GEAGE	Num	Gestational age at birth in weeks	EMPTYSTATE.	
GEAGE_DEC	Char	Gestational age at birth in weeks (displ		
HAWAII	Char	Native Hawaiian or Other Pacific Islande		
NATIVE	Char	American Indian or Alaska Native		
PAGEID	Num	Page Id		
PAGELMBY	Char	Page Last Modified By		REDACT
PAGELMDT	Num	StudyDay of Page Last Modified Date		
PAGENAME	Char	Page Name		
PAGESEQ	Num	Page Seq		
RACEOTH	Char	Other Race, specify		
RCOTHER	Char	Other		
SEX	Char	Sex	\$SEX.	
SEX_DEC	Char	Sex (display value)		
SITENUM	Char	Site Number		REDACT
STATUSID	Num	Page Status Id	DESPGST.	
STATUSID_DEC	Char	Page Status Id (display value)		
VISITID	Num	Visit Id		
VISITSEQ	Num	Visit Seq		
VISNAME	Char	Visit Name		
WHITE	Char	White		
YRSMTHS	Num	Is patient more than 12 months old at th	YN.	
YRSMTHS_DEC	Char	Is patient more than 12 months old at th		

## DOSE

Variable	Type	Label	Format	Redacted
DEIDNUM	Num	Deidentified subject id		
ADMIN1	Num	Dose Administered (mg)		
ADMIN2	Num	Dose Administered (mg)		
ADMIN3	Num	Dose Administered (mg)		
ADMIN4	Num	Dose Administered (mg)		
ADMIN5	Num	Dose Administered (mg)		
ADMIN6	Num	Dose Administered (mg)		
ADMINAD	Num	Dose Administered (mg)		
ASSTDT1	Num	StudyDay of Start Date		
ASSTDT2	Num	StudyDay of Start Date		
ASSTDT3	Num	StudyDay of Start Date		
ASSTDT4	Num	StudyDay of Start Date		
ASSTDT5	Num	StudyDay of Start Date		
ASSTDT6	Num	StudyDay of Start Date		
ASSTDTAD	Num	StudyDay of Start Date		
ASSTTM1	Num	Start Time	TIME5.	
ASSTTM2	Num	Start Time	TIME5.	
ASSTTM3	Num	Start Time	TIME5.	
ASSTTM4	Num	Start Time	TIME5.	
ASSTTM5	Num	Start Time	TIME5.	
ASSTTM6	Num	Start Time	TIME5.	
ASSTTMAD	Num	Start Time	TIME5.	
DATALMBY	Char	Data Last Modified By		REDACT
DATALMDT	Num	StudyDay of Data Last Modified Date		
DAYND1	Char	Please check if Dose 1 not administered		
DAYND2	Char	Please check if Dose 2 not administered		
DAYND3	Char	Please check if Dose 3 not administered		
DAYND4	Char	Please check if Dose 4 not administered		
DAYND5	Char	Please check if Dose 5 not administered		
DAYND6	Char	Please check if Dose 6 not administered		
DAYNDAD	Char	Please check if Additional Dose not admi		
DELETED	Char	Marked Deleted		
DOSEWT	Num	Dose weight (kg)		
FNSPDT1	Num	StudyDay of Final Stop Date		
FNSPDT2	Num	StudyDay of Final Stop Date		
FNSPDT3	Num	StudyDay of Final Stop Date		

## DOSE

Variable	Type	Label	Format	Redacted
FNSPDT4	Num	StudyDay of Final Stop Date		
FNSPDT5	Num	StudyDay of Final Stop Date		
FNSPDT6	Num	StudyDay of Final Stop Date		
FNSPDTAD	Num	StudyDay of Final Stop Date		
FNSPTM1	Num	Final Stop Time	TIME5.	
FNSPTM2	Num	Final Stop Time	TIME5.	
FNSPTM3	Num	Final Stop Time:	TIME5.	
FNSPTM4	Num	Final Stop Time:	TIME5.	
FNSPTM5	Num	Final Stop Time:	TIME5.	
FNSPTM6	Num	Final Stop Time	TIME5.	
FNSPTMAD	Num	Final Stop Time	TIME5.	
INFRT1	Num	Infusion rate (mg/hour)		
INFRT2	Num	Infusion rate (mg/hour)		
INFRT3	Num	Infusion rate (mg/hour)		
INFRT4	Num	Infusion rate (mg/hour)		
INFRT5	Num	Infusion rate (mg/hour)		
INFRT6	Num	Infusion rate (mg/hour)		
INFRTAD	Num	Infusion rate (mg/hour)		
INFRTRE1	Num	Infusion rate (mg/hour)		
INFRTRE2	Num	Infusion rate (mg/hour)		
INFRTRE3	Num	Infusion rate (mg/hour)		
INFRTRE4	Num	Infusion rate (mg/hour)		
INFRTRE5	Num	Infusion rate (mg/hour)		
INFRTRE6	Num	Infusion rate (mg/hour)		
INFRTREA	Num	Infusion rate (mg/hour)		
INTDT1	Num	StudyDay of Interrupted Stop Date:		
INTDT2	Num	StudyDay of Interrupted Stop Date:		
INTDT3	Num	StudyDay of Interrupted Stop Date:		
INTDT4	Num	StudyDay of Interrupted Stop Date:		
INTDT5	Num	StudyDay of Interrupted Stop Date:		
INTDT6	Num	StudyDay of Interrupted Stop Date		
INTDTAD	Num	StudyDay of Interrupted Stop Date:		
INTRPT1	Num	Dosing Interrupted?	YN.	
INTRPT1_DEC	Char	Dosing Interrupted? (display value)		
INTRPT2	Num	Dosing Interrupted?	YN.	
INTRPT2_DEC	Char	Dosing Interrupted? (display value)		

## DOSE

Variable	Type	Label	Format	Redacted
INTRPT3	Num	Dosing Interrupted?	YN.	
INTRPT3_DEC	Char	Dosing Interrupted? (display value)		
INTRPT4	Num	Dosing Interrupted?	YN.	
INTRPT4_DEC	Char	Dosing Interrupted? (display value)		
INTRPT5	Num	Dosing Interrupted?	YN.	
INTRPT5_DEC	Char	Dosing Interrupted? (display value)		
INTRPT6	Num	Dosing Interrupted	YN.	
INTRPT6_DEC	Char	Dosing Interrupted (display value)		
INTRPTAD	Num	Dosing Interrupted?	YN.	
INTRPTAD_DEC	Char	Dosing Interrupted? (display value)		
INTTM1	Num	Interrupted Stop Time:	TIME5.	
INTTM2	Num	Interrupted Stop Time:	TIME5.	
INTTM3	Num	Interrupted Stop Time:	TIME5.	
INTTM4	Num	Interrupted Stop Time:	TIME5.	
INTTM5	Num	Interrupted Stop Time:	TIME5.	
INTTM6	Num	Interrupted Stop Time	TIME5.	
INTTMAD	Num	Interrupted Stop Time:	TIME5.	
ORENTDS1	Num	Did patient vomit/spit up within one hou	YN.	
ORENTDS1_DEC	Char	Did patient vomit/spit up within one hou		
ORENTDS2	Num	Did patient vomit/spit up within one hou	YN.	
ORENTDS2_DEC	Char	Did patient vomit/spit up within one hou		
ORENTDS3	Num	Did patient vomit/spit up within one hou	YN.	
ORENTDS3_DEC	Char	Did patient vomit/spit up within one hou		
ORENTDS4	Num	Did patient vomit/spit up within one hou	YN.	
ORENTDS4_DEC	Char	Did patient vomit/spit up within one hou		
ORENTDS5	Num	Did patient vomit/spit up within one hou	YN.	
ORENTDS5_DEC	Char	Did patient vomit/spit up within one hou		
ORENTDS6	Num	Did patient vomit/spit up within one hou	YN.	
ORENTDS6_DEC	Char	Did patient vomit/spit up within one hou		
ORENTDSA	Num	Did patient vomit/spit up within one hou	YN.	
ORENTDSA_DEC	Char	Did patient vomit/spit up within one hou		
PAGEID	Num	Page Id		
PAGELMBY	Char	Page Last Modified By		REDACT
PAGELMDT	Num	StudyDay of Page Last Modified Date		
PAGENAME	Char	Page Name		
PAGESEQ	Num	Page Seq		

## DOSE

Variable	Type	Label	Format	Redacted
PERVOM1	Num	What percentage of dose is estimated to		
PERVOM2	Num	What percentage of dose is estimated to		
PERVOM3	Num	What percentage of dose is estimated to		
PERVOM4	Num	What percentage of dose is estimated to		
PERVOM5	Num	What percentage of dose is estimated to		
PERVOM6	Num	What percentage of dose is estimated to		
PERVOMAD	Num	What percentage of dose is estimated to		
PKFLSH1	Char	Flush 1		
PKFLSH2	Char	Flush 2		
PKFLSH3	Char	Flush 3		
PKFLSH4	Char	Flush 4		
PKFLSH5	Char	Flush 5		
PKFLSH6	Char	Flush 6		
PKFLSH7	Char	Flush 7		
PKSMP1DT	Num	StudyDay of Sample 1 date		
PKSMP1ND	Char	Sample 1 not done		
PKSMP1NM	Char	Sample 1 accession number (set length to \$2)		
PKSMP1TM	Num	Sample 1 time	TIME5.	
PKSMP2DT	Num	StudyDay of Sample 2 date		
PKSMP2ND	Char	Sample 2 not done		
PKSMP2NM	Char	Sample 2 accession number (set length to \$2)		
PKSMP2TM	Num	Sample 2 time	TIME5.	
PKSMP3DT	Num	StudyDay of Sample 3 date		
PKSMP3ND	Char	Sample 3 not done		
PKSMP3NM	Char	Sample 3 accession number (set length to \$2)		
PKSMP3TM	Num	Sample 3 time	TIME5.	
PKSMP4DT	Num	StudyDay of Sample 4 Date		
PKSMP4ND	Char	Sample 4 not done		
PKSMP4NM	Char	Sample 4 accession number (set length to \$2)		
PKSMP4TM	Num	Sample 4 Time	TIME5.	
PKSMP5DT	Num	StudyDay of Sample 5 Date		
PKSMP5ND	Char	Sample 5 not done		
PKSMP5NM	Char	Sample 5 accession number (set length to \$2)		
PKSMP5TM	Num	Sample 5 Time	TIME5.	
PKSMP6DT	Num	StudyDay of Sample 6 Date		
PKSMP6ND	Char	Sample 6 not done		

## DOSE

Variable	Type	Label	Format	Redacted
PKSMP6NM	Char	Sample 6 accession number (set length to \$2)		
PKSMP6TM	Num	Sample 6 Time	TIME5.	
PKSMP7DT	Num	StudyDay of Sample 7 Date		
PKSMP7ND	Char	Sample 7 not done		
PKSMP7NM	Char	Sample 7 accession number (set length to \$2)		
PKSMP7TM	Num	Sample 7 Time	TIME5.	
PO1DT	Num	StudyDay of Dose Date		
PO1TM	Num	Dose Time	TIME5.	
PO2DT	Num	StudyDay of Dose Date		
PO2TM	Num	Dose Time	TIME5.	
PO3DT	Num	StudyDay of Dose Date		
PO3TM	Num	Dose Time	TIME5.	
PO4DT	Num	StudyDay of Dose Date		
PO4TM	Num	Dose Time	TIME5.	
PO5DT	Num	StudyDay of Dose Date		
PO5TM	Num	Dose Time	TIME5.	
PO6DT	Num	StudyDay of Dose Date		
PO6TM	Num	Dose Time	TIME5.	
POADDT	Num	StudyDay of Dose Date		
POADTM	Num	Dose Time	TIME5.	
REDOSE1	Num	Dose Administered (mg)		
REDOSE2	Num	Dose Administered (mg)		
REDOSE3	Num	Dose Administered (mg)		
REDOSE4	Num	Dose Administered (mg)		
REDOSE5	Num	Dose Administered (mg)		
REDOSE6	Num	Dose Administered (mg)		
REDOSEAD	Num	Dose Administered (mg)		
REDS1DT	Num	StudyDay of Re-dose Date		
REDS1EST	Char	Please check if time given is estimated		
REDS1TM	Num	Re-dose Time	TIME5.	
REDS1YN	Num	Was patient re-dosed?	YN.	
REDS1YN_DEC	Char	Was patient re-dosed? (display value)		
REDS2DT	Num	StudyDay of Re-dose Date		
REDS2EST	Char	Please check if time given is estimated		
REDS2TM	Num	Re-dose Time	TIME5.	
REDS2YN	Num	Was patient re-dosed?	YN.	

## DOSE

Variable	Type	Label	Format	Redacted
REDS2YN_DEC	Char	Was patient re-dosed? (display value)		
REDS3DT	Num	StudyDay of Re-dose Date		
REDS3EST	Char	Please check if time given is estimated		
REDS3TM	Num	Re-dose Time	TIME5.	
REDS3YN	Num	Was patient re-dosed?	YN.	
REDS3YN_DEC	Char	Was patient re-dosed? (display value)		
REDS4DT	Num	StudyDay of Re-dose Date		
REDS4EST	Char	Please check if time given is estimated		
REDS4TM	Num	Re-dose Time	TIME5.	
REDS4YN	Num	Was patient re-dosed?	YN.	
REDS4YN_DEC	Char	Was patient re-dosed? (display value)		
REDS5DT	Num	StudyDay of Re-dose Date		
REDS5EST	Char	Please check if time given is estimated		
REDS5TM	Num	Re-dose Time	TIME5.	
REDS5YN	Num	Was patient re-dosed?	YN.	
REDS5YN_DEC	Char	Was patient re-dosed? (display value)		
REDS6DT	Num	StudyDay of Re-dose Date		
REDS6EST	Char	Please check if time given is estimated		
REDS6TM	Num	Re-dose Time	TIME5.	
REDS6YN	Num	Was patient re-dosed?	YN.	
REDS6YN_DEC	Char	Was patient re-dosed? (display value)		
REDSADDT	Num	StudyDay of Re-dose Date		
REDSADTM	Num	Re-dose Time	TIME5.	
REDSADYN	Num	Was patient re-dosed?	YN.	
REDSADYN_DEC	Char	Was patient re-dosed? (display value)		
REDSAEST	Char	Please check if time given is estimated		
RESTRT1	Num	Dosing Restarted?	YN.	
RESTRT1_DEC	Char	Dosing Restarted? (display value)		
RESTRT2	Num	Dosing Restarted?	YN.	
RESTRT2_DEC	Char	Dosing Restarted? (display value)		
RESTRT3	Num	Dosing Restarted?	YN.	
RESTRT3_DEC	Char	Dosing Restarted? (display value)		
RESTRT4	Num	Dosing Restarted?	YN.	
RESTRT4_DEC	Char	Dosing Restarted? (display value)		
RESTRT5	Num	Dosing Restarted?	YN.	
RESTRT5_DEC	Char	Dosing Restarted? (display value)		



## DOSE

Variable	Type	Label	Format	Redacted
RESTRT6	Num	Dosing Restarted?	YN.	
RESTRT6_DEC	Char	Dosing Restarted? (display value)		
RESTRTAD	Num	Dosing Restarted?	YN.	
RESTRTAD_DEC	Char	Dosing Restarted? (display value)		
ROTHSY1	Char	Other, specify:		
ROTHSY2	Char	Other, specify:		
ROTHSY3	Char	Other, specify:		
ROTHSY4	Char	Other, specify:		
ROTHSY5	Char	Other, specify:		
ROTHSY6	Char	Other, specify:		
ROTHSYAD	Char	Other, specify:		
ROUTE1	Num	Route Administered	ROUTE.	
ROUTE1_DEC	Char	Route Administered (display value)		
ROUTE2	Num	Route Administered	ROUTE.	
ROUTE2_DEC	Char	Route Administered (display value)		
ROUTE3	Num	Route Administered	ROUTE.	
ROUTE3_DEC	Char	Route Administered (display value)		
ROUTE4	Num	Route Administered	ROUTE.	
ROUTE4_DEC	Char	Route Administered (display value)		
ROUTE5	Num	Route Administered	ROUTE.	
ROUTE5_DEC	Char	Route Administered (display value)		
ROUTE6	Num	Route Administered	ROUTE.	
ROUTE6_DEC	Char	Route Administered (display value)		
ROUTEAD	Num	Route Administered	ROUTE.	
ROUTEAD_DEC	Char	Route Administered (display value)		
RSNAD1	Num	Reason not administered:	REASON_6M.	
RSNAD1_DEC	Char	Reason not administered: (display value)		
RSNAD2	Num	Reason not administered:	REASON_6M.	
RSNAD2_DEC	Char	Reason not administered: (display value)		
RSNAD3	Num	Reason not administered:	REASON_6M.	
RSNAD3_DEC	Char	Reason not administered: (display value)		
RSNAD4	Num	Reason not administered:	REASON_6M.	
RSNAD4_DEC	Char	Reason not administered: (display value)		
RSNAD5	Num	Reason not administered:	REASON_6M.	
RSNAD5_DEC	Char	Reason not administered: (display value)		
RSNAD6	Num	Reason not administered:	REASON_6M.	

## DOSE

Variable	Type	Label	Format	Redacted
RSNAD6_DEC	Char	Reason not administered: (display value)		
RSNADAD	Num	Reason not administered:	REASON_6M.	
RSNADAD_DEC	Char	Reason not administered: (display value)		
RSTRDT1	Num	StudyDay of Restarted Date:		
RSTRDT2	Num	StudyDay of Restarted Date:		
RSTRDT3	Num	StudyDay of Restarted Date:		
RSTRDT4	Num	StudyDay of Restarted Date:		
RSTRDT5	Num	StudyDay of Restarted Date:		
RSTRDT6	Num	StudyDay of Restarted Date		
RSTRDTAD	Num	StudyDay of Restarted Date:		
RSTRTM1	Num	Restarted Time:	TIME5.	
RSTRTM2	Num	Restarted Time:	TIME5.	
RSTRTM3	Num	Restarted Time:	TIME5.	
RSTRTM4	Num	Restarted Time:	TIME5.	
RSTRTM5	Num	Restarted Time:	TIME5.	
RSTRTM6	Num	Restarted Time	TIME5.	
RSTRTMAD	Num	Restarted Time:	TIME5.	
RXTKN	Num	Which drug is patient taking?	IP.	
RXTKN_DEC	Char	Which drug is patient taking? (display v		
SITENUM	Char	Site Number		REDACT
STATUSID	Num	Page Status Id	DESPGST.	
STATUSID_DEC	Char	Page Status Id (display value)		
STTM1EST	Char	Please check if time given is estimated		
STTM2EST	Char	Please check if time given is estimated		
STTM3EST	Char	Please check if time given is estimated		
STTM4EST	Char	Please check if time given is estimated		
STTM5EST	Char	Please check if time given is estimated		
STTM6EST	Char	Please check if time given is estimated		
STTMAEST	Char	Please check if time given is estimated		
TYPE1	Num	Type	CAPSSUSP.	
TYPE1_DEC	Char	Type (display value)		
TYPE2	Num	Type	CAPSSUSP.	
TYPE2_DEC	Char	Type (display value)		
TYPE3	Num	Type	CAPSSUSP.	
TYPE3_DEC	Char	Type (display value)		
TYPE4	Num	Type	CAPSSUSP.	

## DOSE

Variable	Type	Label	Format	Redacted
TYPE4_DEC	Char	Type (display value)		
TYPE5	Num	Type	CAPSSUSP.	
TYPE5_DEC	Char	Type (display value)		
TYPE6	Num	Type	CAPSSUSP.	
TYPE6_DEC	Char	Type (display value)		
TYPEAD	Num	Type	CAPSSUSP.	
TYPEAD_DEC	Char	Type (display value)		
VISITID	Num	Visit Id		
VISITSEQ	Num	Visit Seq		
VISNAME	Char	Visit Name		

## DS

Variable	Type	Label	Format	Redacted
DEIDNUM	Num	Deidentified subject id		
DATALMBY	Char	Data Last Modified By		REDACT
DATALMDT	Num	StudyDay of Data Last Modified Date		
DELETED	Char	Marked Deleted		
DISCYN	Num	Did subject discontinue the study early?	YESNO_LIB.	
DISCYN_DEC	Char	Did subject discontinue the study early?		
DSSTDT	Char	Date of Discontinuation		
DSTERM	Num	Reason for Discontinuation	NCOMPLT.	
DSTERM_DEC	Char	Reason for Discontinuation (display valu		
PAGEID	Num	Page Id		
PAGELMBY	Char	Page Last Modified By		REDACT
PAGELMDT	Num	StudyDay of Page Last Modified Date		
PAGENAME	Char	Page Name		
PAGESEQ	Num	Page Seq		
SITENUM	Char	Site Number		REDACT
STATUSID	Num	Page Status Id	DESPGST.	
STATUSID_DEC	Char	Page Status Id (display value)		
VISITID	Num	Visit Id		
VISITSEQ	Num	Visit Seq		
VISNAME	Char	Visit Name		

## HLAB

Variable	Type	Label	Format	Redacted
DEIDNUM	Num	Deidentified subject id		
DATALMBY	Char	Data Last Modified By		REDACT
DATALMDT	Num	StudyDay of Data Last Modified Date		
DELETED	Char	Marked Deleted		
HCTDT	Num	StudyDay of Hematocrit date		
HCTND	Num	Hematocrit done	YESNO.	
HCTND_DEC	Char	Hematocrit done (display value)		
HCTRSLT	Num	Hematocrit Results	NORMALCLINABNORMAL_LIB.	
HCTRSLT_DEC	Char	Hematocrit Results (display value)		
HCTSM	Char	Hematocrit same date and time		
HCTTM	Num	Hematocrit time	TIME5.	
HCTUNIT	Num	Hematocrit unit	HCTU.	
HCTUNIT_DEC	Char	Hematocrit unit (display value)		
HCTVAL	Num	Hematocrit value		
HGBDT	Num	StudyDay of Hemoglobin date		
HGBND	Num	Hemoglobin done	YESNO.	
HGBND_DEC	Char	Hemoglobin done (display value)		
HGBRSLT	Num	Hemoglobin Results	NORMALCLINABNORMAL_LIB.	
HGBRSLT_DEC	Char	Hemoglobin Results (display value)		
HGBSM	Char	Hemoglobin same date and time		
HGBTM	Num	Hemoglobin time	TIME5.	
HGBUNIT	Num	Hemoglobin unit	HGBU.	
HGBUNIT_DEC	Char	Hemoglobin unit (display value)		
HGBVAL	Num	Hemoglobin value		
LABDT	Num	StudyDay of Lab date		
LABNAME	Char	Lab Name		REDACT
LABTM	Num	Lab time	TIME5.	
LLABND	Char	Check box if labs were not done		
PAGEID	Num	Page Id		
PAGELMBY	Char	Page Last Modified By		REDACT
PAGELMDT	Num	StudyDay of Page Last Modified Date		
PAGENAME	Char	Page Name		
PAGESEQ	Num	Page Seq		
PLTDT	Num	StudyDay of Platelet Count date		
PLTND	Num	Platelet Count done	YESNO.	

## HLAB

Variable	Type	Label	Format	Redacted
PLTND_DEC	Char	Platelet Count done (display value)		
PLTRSLT	Num	Platelet Count Results	NORMALCLINABNORMAL_LIB.	
PLTRSLT_DEC	Char	Platelet Count Results (display value)		
PLTSM	Char	Platelet Count same date and time		
PLTTM	Num	Platelet Count time	TIME5.	
PLTUNT	Num	Platelet Count unit	PLTCU_5M.	
PLTUNT_DEC	Char	Platelet Count unit (display value)		
PLTVAL	Num	Platelet Count value		
SITENUM	Char	Site Number		REDACT
STATUSID	Num	Page Status Id	DESPGST.	
STATUSID_DEC	Char	Page Status Id (display value)		
VISITID	Num	Visit Id		
VISITSEQ	Num	Visit Seq		
VISNAME	Char	Visit Name		
WBCDT	Num	StudyDay of WBC Count date		
WBCND	Num	WBC Count done	YESNO.	
WBCND_DEC	Char	WBC Count done (display value)		
WBCRSLT	Num	WBC Count Results	NORMALCLINABNORMAL_LIB.	
WBCRSLT_DEC	Char	WBC Count Results (display value)		
WBCSM	Char	WBC Count same date and time		
WBC TM	Num	WBC Count time	TIME5.	
WBCUNT	Num	WBC Count unit	WBCU.	
WBCUNT_DEC	Char	WBC Count unit (display value)		
WBCVAL	Num	WBC Count value		

## IE

Variable	Type	Label	Format	Redacted
DEIDNUM	Num	Deidentified subject id		
ASSENTDT	Num	StudyDay of Date assent signed by patient		
ASSENTYN	Num	Was assent signed by patient?	YN.	
ASSENTYN_DEC	Char	Was assent signed by patient? (display v		
DATALMBY	Char	Data Last Modified By		REDACT
DATALMDT	Num	StudyDay of Data Last Modified Date		
DELETED	Char	Marked Deleted		
EXCNM1	Char	1. Allergy		
EXCNM2	Char	2. For clindamycin, treatment with stron		
EXCNM3	Char	3. Serum creatinine >2 mg/dl within 48 h		
EXCNM4	Char	4. Known ALT >250 U/L or AST >500 U/L on		
EXCNM5	Char	5. Known pregnancy		
EXCNM6	Char	6. Breastfeeding females		
EXCNM7	Char	7. On extracorporeal membrane oxygenatio		
EXCNM8	Char	8. Any condition that, in the judgment o		
GCONSDT	Num	StudyDay of Date Informed Consent signed by parent/g		
IEMET	Num	Is patient eligible based upon inclusion	YESNO_LIB.	
IEMET_DEC	Char	Is patient eligible based upon inclusion		
INCNM1	Char	1. Informed consent / assent		
INCNM2	Char	2. Prevention/treatment of confirmed/sus		
INCNM3	Char	3. Postmenstrual age (PMA) >36 weeks		
INCNM4	Char	4. Able to take oral drugs (TMP-SMX)		
INCNM5	Char	5. Sufficient IV access for drug adminis		
PAGEID	Num	Page Id		
PAGELMBY	Char	Page Last Modified By		REDACT
PAGELMDT	Num	StudyDay of Page Last Modified Date		
PAGENAME	Char	Page Name		
PAGESEQ	Num	Page Seq		
PRVDRG	Num	Has patient received study drug prior to	PRVDRG.	
PRVDRG_DEC	Char	Has patient received study drug prior to		
SITENUM	Char	Site Number		REDACT
STATUSID	Num	Page Status Id	DESPGST.	
STATUSID_DEC	Char	Page Status Id (display value)		
VISITID	Num	Visit Id		
VISITSEQ	Num	Visit Seq		
VISNAME	Char	Visit Name		

**IE**

<b>Variable</b>	<b>Type</b>	<b>Label</b>	<b>Format</b>	<b>Redacted</b>
WAIVER	Num	Was a waiver granted?	YESNO_LIB.	
WAIVER_DEC	Char	Was a waiver granted? (display value)		
WAVRDT	Num	StudyDay of Date waiver granted		
WVRAPP	Char	Name of person granting waiver		



## MH

Variable	Type	Label	Format	Redacted
DEIDNUM	Num	Deidentified subject id		
DATALMBY	Char	Data Last Modified By		REDACT
DATALMDT	Num	StudyDay of Data Last Modified Date		
DELETED	Char	Marked Deleted		
MHBODSPC	Char	Other specify		
MHBODSYS	Num	Body System	BS.	
MHBODSYS_DEC	Char	Body System (display value)		
MHENDT	Num	StudyDay of Stop Date		
MHONG	Num	Ongoing	ONGOING.	
MHONG_DEC	Char	Ongoing (display value)		
MHPREF	Num	Has the subject experienced any past and	YESNO_LIB.	
MHPREF_DEC	Char	Has the subject experienced any past and		
MHSTDT	Num	StudyDay of Start Date		
MHTERM	Char	Condition/Event		
PAGEID	Num	Page Id		
PAGELMBY	Char	Page Last Modified By		REDACT
PAGELMDT	Num	StudyDay of Page Last Modified Date		
PAGENAME	Char	Page Name		
PAGESEQ	Num	Page Seq		
SITENUM	Char	Site Number		REDACT
STATUSID	Num	Page Status Id	DESPGST.	
STATUSID_DEC	Char	Page Status Id (display value)		
VISITID	Num	Visit Id		
VISITSEQ	Num	Visit Seq		
VISNAME	Char	Visit Name		

## OPPK

Variable	Type	Label	Format	Redacted
DEIDNUM	Num	Deidentified subject id		
DATALMBY	Char	Data Last Modified By		REDACT
DATALMDT	Num	StudyDay of Data Last Modified Date		
DELETED	Char	Marked Deleted		
OPPKDT	Num	StudyDay of Date of sample collection		
OPPKTM	Char	Time of sample collection	\$EMPTYSTATE.	
OPPKTM_DEC	Char	Time of sample collection (display value)		
OPPKTYP	Num	Sample type	OPPKTP.	
OPPKTYP_DEC	Char	Sample type (display value)		
PAGEID	Num	Page Id		
PAGELMBY	Char	Page Last Modified By		REDACT
PAGELMDT	Num	StudyDay of Page Last Modified Date		
PAGENAME	Char	Page Name		
PAGESEQ	Num	Page Seq		
SITENUM	Char	Site Number		REDACT
STATUSID	Num	Page Status Id	DESPGST.	
STATUSID_DEC	Char	Page Status Id (display value)		
VISITID	Num	Visit Id		
VISITSEQ	Num	Visit Seq		
VISNAME	Char	Visit Name		

**PE**

<b>Variable</b>	<b>Type</b>	<b>Label</b>	<b>Format</b>	<b>Redacted</b>
DEIDNUM	Num	Deidentified subject id		
DATALMBY	Char	Data Last Modified By		REDACT
DATALMDT	Num	StudyDay of Data Last Modified Date		
DELETED	Char	Marked Deleted		
HEIGHT	Num	Height/length (in centimeters)	EMPTYSTATE.	
HEIGHT_DEC	Char	Height/length (in centimeters) (display		
PAGEID	Num	Page Id		
PAGELMBY	Char	Page Last Modified By		REDACT
PAGELMDT	Num	StudyDay of Page Last Modified Date		
PAGENAME	Char	Page Name		
PAGESEQ	Num	Page Seq		
PEDESC	Char	GA - Abnormal Results		
PEDESC1	Char	NL - Abnormal Results		
PEDESC11	Char	ED - Abnormal Results		
PEDESC2	Char	HS - Abnormal Results		
PEDESC3	Char	LP - Abnormal Results		
PEDESC4	Char	ENT - Abnormal Results		
PEDESC5	Char	RS - Abnormal Results		
PEDESC6	Char	CV - Abnormal Results		
PEDESC7	Char	AB - Abnormal Results		
PEDESC8	Char	SM - Abnormal Results		
PEDESC9	Char	MS - Abnormal Results		
PEDESC98	Char	OTH - Abnormal Results		
PEDT	Num	StudyDay of Physical Exam Date		
PEORRES	Num	GA - Results	NORMALCLINABNORMAL_LIB.	
PEORRES1	Num	NL - Results	NORMALCLINABNORMAL_LIB.	
PEORRES11	Num	ED - Results	NORMALCLINABNORMAL_LIB.	
PEORRES11_DEC	Char	ED - Results (display value)		
PEORRES1_DEC	Char	NL - Results (display value)		
PEORRES2	Num	HS - Results	NORMALCLINABNORMAL_LIB.	
PEORRES2_DEC	Char	HS - Results (display value)		
PEORRES3	Num	LP - Results	NORMALCLINABNORMAL_LIB.	
PEORRES3_DEC	Char	LP - Results (display value)		

**PE**

<b>Variable</b>	<b>Type</b>	<b>Label</b>	<b>Format</b>	<b>Redacted</b>
PEORRES4	Num	ENT - Results	NORMALCLINABNORMAL_LIB.	
PEORRES4_DEC	Char	ENT - Results (display value)		
PEORRES5	Num	RS - Results	NORMALCLINABNORMAL_LIB.	
PEORRES5_DEC	Char	RS - Results (display value)		
PEORRES6	Num	CV - Results	NORMALCLINABNORMAL_LIB.	
PEORRES6_DEC	Char	CV - Results (display value)		
PEORRES7	Num	AB - Results	NORMALCLINABNORMAL_LIB.	
PEORRES7_DEC	Char	AB - Results (display value)		
PEORRES8	Num	SM - Results	NORMALCLINABNORMAL_LIB.	
PEORRES8_DEC	Char	SM - Results (display value)		
PEORRES9	Num	MS - Results	NORMALCLINABNORMAL_LIB.	
PEORRES98	Num	OTH - Results	NORMALCLINABNORMAL_LIB.	
PEORRES98_DEC	Char	OTH - Results (display value)		
PEORRES9_DEC	Char	MS - Results (display value)		
PEORRES_DEC	Char	GA - Results (display value)		
SITENUM	Char	Site Number		REDACT
STATUSID	Num	Page Status Id	DESPGST.	
STATUSID_DEC	Char	Page Status Id (display value)		
VISITID	Num	Visit Id		
VISITSEQ	Num	Visit Seq		
VISNAME	Char	Visit Name		
WEIGHT	Num	Actual weight (in kilograms)		

## PKU

Variable	Type	Label	Format	Redacted
DEIDNUM	Num	Deidentified subject id		
DATALMBY	Char	Data Last Modified By		REDACT
DATALMDT	Num	StudyDay of Data Last Modified Date		
DELETED	Char	Marked Deleted		
PAGEID	Num	Page Id		
PAGELMBY	Char	Page Last Modified By		REDACT
PAGELMDT	Num	StudyDay of Page Last Modified Date		
PAGENAME	Char	Page Name		
PAGESEQ	Num	Page Seq		
PKUACCNO	Char	Sample accession number (set length to \$8)	\$EMPTYSTATE.	
PKUACCNO_DEC	Char	Sample accession number (display value)		
PKUDIAP	Num	Does patient wear diapers?	YESNO.	
PKUDIAP_DEC	Char	Does patient wear diapers? (display valu		
PKUDPWT	Num	Diaper weight (g)	EMPTYSTATE.	
PKUDPWT_DEC	Char	Diaper weight (g) (display value)		
PKUDT	Num	StudyDay of Collection date		
PKUESTTM	Char	Please check if time given is estimated		
PKUNC	Char	Not Collected		
PKUPRVDT	Num	StudyDay of Date of previous urine output.		
PKUPRVTM	Char	Time of previous urine output.	\$EMPTYSTATE.	
PKUPRVTM_DEC	Char	Time of previous urine output. (display		
PKUTM	Char	Collection time	\$EMPTYSTATE.	
PKUTM_DEC	Char	Collection time (display value)		
PKUVOL	Num	Volume (mL)	EMPTYSTATE.	
PKUVOL_DEC	Char	Volume (mL) (display value)		
SITENUM	Char	Site Number		REDACT
STATUSID	Num	Page Status Id	DESPGST.	
STATUSID_DEC	Char	Page Status Id (display value)		
VISITID	Num	Visit Id		
VISITSEQ	Num	Visit Seq		
VISNAME	Char	Visit Name		

## PRVDRG

Variable	Type	Label	Format	Redacted
DEIDNUM	Num	Deidentified subject id		
DATALMBY	Char	Data Last Modified By		REDACT
DATALMDT	Num	StudyDay of Data Last Modified Date		
DELETED	Char	Marked Deleted		
INFRAT1	Num	Infusion rate (mg/hour)	EMPTYSTATE.	
INFRAT1_DEC	Char	Infusion rate (mg/hour) (display value)		
INFRAT2	Num	Infusion rate (mg/hour)	EMPTYSTATE.	
INFRAT2_DEC	Char	Infusion rate (mg/hour) (display value)		
INFRAT3	Num	Infusion rate (mg/hour)	EMPTYSTATE.	
INFRAT3_DEC	Char	Infusion rate (mg/hour) (display value)		
INFRAT4	Num	Infusion rate (mg/hour)	EMPTYSTATE.	
INFRAT4_DEC	Char	Infusion rate (mg/hour) (display value)		
INFRAT5	Num	Infusion rate (mg/hour)	EMPTYSTATE.	
INFRAT5_DEC	Char	Infusion rate (mg/hour) (display value)		
INFRAT6	Num	Infusion rate (mg/hour)	EMPTYSTATE.	
INFRAT6_DEC	Char	Infusion rate (mg/hour) (display value)		
PAGEID	Num	Page Id		
PAGELMBY	Char	Page Last Modified By		REDACT
PAGELMDT	Num	StudyDay of Page Last Modified Date		
PAGENAME	Char	Page Name		
PAGESEQ	Num	Page Seq		
PRV1DT	Num	StudyDay of Date		
PRV1ENDT	Num	StudyDay of End date		
PRV1ENTM	Char	End time	\$EMPTYSTATE.	
PRV1ENTM_DEC	Char	End time (display value)		
PRV1RT	Num	Route	ROUTE.	
PRV1RT_DEC	Char	Route (display value)		
PRV1STDT	Num	StudyDay of Start date		
PRV1STTM	Char	Start time	\$EMPTYSTATE.	
PRV1STTM_DEC	Char	Start time (display value)		
PRV1TM	Char	Time	\$EMPTYSTATE.	
PRV1TM_DEC	Char	Time (display value)		
PRV1TYP	Num	Type	CAPSSUSP.	
PRV1TYP_DEC	Char	Type (display value)		
PRV2DT	Num	StudyDay of Date		
PRV2ENDT	Num	StudyDay of End date		

## PRVDRG

Variable	Type	Label	Format	Redacted
PRV2ENTM	Char	End time	\$EMPTYSTATE.	
PRV2ENTM_DEC	Char	End time (display value)		
PRV2RT	Num	Route	ROUTE.	
PRV2RT_DEC	Char	Route (display value)		
PRV2STDT	Num	StudyDay of Start date		
PRV2STTM	Char	Start time	\$EMPTYSTATE.	
PRV2STTM_DEC	Char	Start time (display value)		
PRV2TM	Char	Time	\$EMPTYSTATE.	
PRV2TM_DEC	Char	Time (display value)		
PRV2TYP	Num	Type	CAPSSUSP.	
PRV2TYP_DEC	Char	Type (display value)		
PRV3DT	Num	StudyDay of Date		
PRV3ENDT	Num	StudyDay of End date		
PRV3ENTM	Char	End time	\$EMPTYSTATE.	
PRV3ENTM_DEC	Char	End time (display value)		
PRV3RT	Num	Route	ROUTE.	
PRV3RT_DEC	Char	Route (display value)		
PRV3STDT	Num	StudyDay of Start date		
PRV3STTM	Char	Start time	\$EMPTYSTATE.	
PRV3STTM_DEC	Char	Start time (display value)		
PRV3TM	Char	Time	\$EMPTYSTATE.	
PRV3TM_DEC	Char	Time (display value)		
PRV3TYP	Num	Type	CAPSSUSP.	
PRV3TYP_DEC	Char	Type (display value)		
PRV4DT	Num	StudyDay of Date		
PRV4ENDT	Num	StudyDay of End date		
PRV4ENTM	Char	End time	\$EMPTYSTATE.	
PRV4ENTM_DEC	Char	End time (display value)		
PRV4RT	Num	Route	ROUTE.	
PRV4RT_DEC	Char	Route (display value)		
PRV4STDT	Num	StudyDay of Start date		
PRV4STTM	Char	Start time	\$EMPTYSTATE.	
PRV4STTM_DEC	Char	Start time (display value)		
PRV4TM	Char	Time	\$EMPTYSTATE.	
PRV4TM_DEC	Char	Time (display value)		
PRV4TYP	Num	Type	CAPSSUSP.	

## PRVDRG

Variable	Type	Label	Format	Redacted
PRV4TYP_DEC	Char	Type (display value)		
PRV5DT	Num	StudyDay of Date		
PRV5ENDT	Num	StudyDay of End date		
PRV5ENTM	Char	End time	\$EMPTYSTATE.	
PRV5ENTM_DEC	Char	End time (display value)		
PRV5RT	Num	Route	ROUTE.	
PRV5RT_DEC	Char	Route (display value)		
PRV5STDT	Num	StudyDay of Start date		
PRV5STTM	Char	Start time	\$EMPTYSTATE.	
PRV5STTM_DEC	Char	Start time (display value)		
PRV5TM	Char	Time	\$EMPTYSTATE.	
PRV5TM_DEC	Char	Time (display value)		
PRV5TYP	Num	Type	CAPSSUSP.	
PRV5TYP_DEC	Char	Type (display value)		
PRV6DT	Num	StudyDay of Date		
PRV6ENDT	Num	StudyDay of End date		
PRV6ENTM	Char	End time	\$EMPTYSTATE.	
PRV6ENTM_DEC	Char	End time (display value)		
PRV6RT	Num	Route	ROUTE.	
PRV6RT_DEC	Char	Route (display value)		
PRV6STDT	Num	StudyDay of Start date		
PRV6STTM	Char	Start time	\$EMPTYSTATE.	
PRV6STTM_DEC	Char	Start time (display value)		
PRV6TM	Char	Time	\$EMPTYSTATE.	
PRV6TM_DEC	Char	Time (display value)		
PRV6TYP	Num	Type	CAPSSUSP.	
PRV6TYP_DEC	Char	Type (display value)		
PRVDRGNU	Num	How many doses of study drug did patient	PRVDGNU.	
PRVDRGNU_DEC	Char	How many doses of study drug did patient		
SITENUM	Char	Site Number		REDACT
STATUSID	Num	Page Status Id	DESPGST.	
STATUSID_DEC	Char	Page Status Id (display value)		
TOTDS1	Num	Total Dose Administered (mg)		
TOTDS2	Num	Total Dose Administered (mg)		
TOTDS3	Num	Total Dose Administered (mg)		
TOTDS4	Num	Total Dose Administered (mg)		



## PRVDRG

<b>Variable</b>	<b>Type</b>	<b>Label</b>	<b>Format</b>	<b>Redacted</b>
TOTDS5	Num	Total Dose Administered (mg)		
TOTDS6	Num	Total Dose Administered (mg)		
VISITID	Num	Visit Id		
VISITSEQ	Num	Visit Seq		
VISNAME	Char	Visit Name		

**PT**

<b>Variable</b>	<b>Type</b>	<b>Label</b>	<b>Format</b>	<b>Redacted</b>
DEIDNUM	Num	Deidentified subject id		
DATALMBY	Char	Data Last Modified By		REDACT
DATALMDT	Num	StudyDay of Data Last Modified Date		
DELETED	Char	Marked Deleted		
PAGEID	Num	Page Id		
PAGELMBY	Char	Page Last Modified By		REDACT
PAGELMDT	Num	StudyDay of Page Last Modified Date		
PAGENAME	Char	Page Name		
PAGESEQ	Num	Page Seq		
PGPSNG	Num	Result	POSNEG.	
PGPSNG_DEC	Char	Result (display value)		
PGTIME	Num	Collection time	TIME5.	
PGTSTDT	Num	StudyDay of Collection date		
PREGTST	Num	Was pregnancy test performed at this vis	YNNA.	
PREGTST_DEC	Char	Was pregnancy test performed at this vis		
SITENUM	Char	Site Number		REDACT
STATUSID	Num	Page Status Id	DESPGST.	
STATUSID_DEC	Char	Page Status Id (display value)		
VISITID	Num	Visit Id		
VISITSEQ	Num	Visit Seq		
VISNAME	Char	Visit Name		

## SOCD

Variable	Type	Label	Format	Redacted
DEIDNUM	Num	Deidentified subject id		
DATALMBY	Char	Data Last Modified By		REDACT
DATALMDT	Num	StudyDay of Data Last Modified Date		
DELETED	Char	Marked Deleted		
MICB	Num	Were any microbiologic assessments perfo	YESNO.	
MICBACT	Num	Organism	BACTERIA.	
MICBACT_DEC	Char	Organism (display value)		
MICBDT	Num	StudyDay of Date		
MICBSPC	Num	Species	SPECIES.	
MICBSPC_DEC	Char	Species (display value)		
MICBTM	Num	Time	TIME5.	
MICBTYP	Num	Type	TYPE.	
MICBTYP_DEC	Char	Type (display value)		
MICB_DEC	Char	Were any microbiologic assessments perfo		
MICFNGI	Num	Organism	FUNGI.	
MICFNGI_DEC	Char	Organism (display value)		
MICPRA	Num	Organism	PARASITES.	
MICPRA_DEC	Char	Organism (display value)		
MICSPFY	Char	Other, specify		
MICVRS	Num	Organism	VIRUSES.	
MICVRS_DEC	Char	Organism (display value)		
PAGEID	Num	Page Id		
PAGELMBY	Char	Page Last Modified By		REDACT
PAGELMDT	Num	StudyDay of Page Last Modified Date		
PAGENAME	Char	Page Name		
PAGESEQ	Num	Page Seq		
RESULT	Num	Result	POSNEG.	
RESULT_DEC	Char	Result (display value)		
SITENUM	Char	Site Number		REDACT
STATUSID	Num	Page Status Id	DESPGST.	
STATUSID_DEC	Char	Page Status Id (display value)		
VISITID	Num	Visit Id		
VISITSEQ	Num	Visit Seq		
VISNAME	Char	Visit Name		

## SV

Variable	Type	Label	Format	Redacted
DEIDNUM	Num	Deidentified subject id		
DATALMBY	Char	Data Last Modified By		REDACT
DATALMDT	Num	StudyDay of Data Last Modified Date		
DELETED	Char	Marked Deleted		
PAGEID	Num	Page Id		
PAGELMBY	Char	Page Last Modified By		REDACT
PAGELMDT	Num	StudyDay of Page Last Modified Date		
PAGENAME	Char	Page Name		
PAGESEQ	Num	Page Seq		
SITENUM	Char	Site Number		REDACT
STATUSID	Num	Page Status Id	DESPGST.	
STATUSID_DEC	Char	Page Status Id (display value)		
SVDT	Num	StudyDay of Date of visit		
VISITID	Num	Visit Id		
VISITSEQ	Num	Visit Seq		
VISNAME	Char	Visit Name		

## DES\_FORMATS

Format Name	Code Value	Code Label
ACTION	1	Dose not changed
ACTION	2	Dose reduced
ACTION	3	Dose increased
ACTION	4	Drug Interrupted
ACTION	5	Drug discontinued
ACTION	6	Unknown
ACTION	7	Not applicable
AESAE_LAB	1	mmol/L
AESAE_LAB	2	mg/dL
AESAE_LAB	3	%
AESAE_LAB	4	g/dL
AESAE_LAB	5	g/L
AESAE_LAB	6	IU/L or U/L or mIU/mL
AESAE_LAB	7	ukat/L
AESAE_LAB	8	umol/L
AESAE_LAB	9	nkat/L
AESAE_LAB	10	mm <sup>3</sup>
AESAE_LAB	11	mmol/mol
AESAE_LAB	12	mEq
AESAE_LAB	13	µg
AESAE_LAB	14	µg/kg
AESAE_LAB	15	ng/ml or µg/L
AESAE_LAB	16	µg/ml or mg/L
AESAE_LAB	17	µmol
AESAE_LAB	18	g
AESAE_LAB	19	cc
AESAE_LAB	20	min
AESAE_LAB	21	mL
AESAE_LAB	22	Gtt
AESAE_LAB	23	mcg
AESAE_LAB	24	mcg/kg/min
ALBU	11	g/dL
ALBU	12	g/L
ALKPU	2	U/L
ALKPU	5	IU/L
ALTU	2	U/L

## DES\_FORMATS

Format Name	Code Value	Code Label
ALTU	5	IU/L
ASTU	2	U/L
ASTU	5	IU/L
BACTERIA	5	Abiotrophia sp.
BACTERIA	10	Acinetobacter sp.
BACTERIA	15	Actinomyces sp.
BACTERIA	20	Aeromonas sp.
BACTERIA	25	Bacillus sp.
BACTERIA	30	Bacillus cereus
BACTERIA	35	Bacteroides sp.
BACTERIA	40	Bacteroides fragilis
BACTERIA	45	Bordetella pertussis
BACTERIA	50	Burkholderia cepacia
BACTERIA	55	Campylobacter jejuni
BACTERIA	60	Chlamydia pneumoniae
BACTERIA	65	Chlamydia trachomatis
BACTERIA	70	Citrobacter sp.
BACTERIA	75	Clostridia sp.
BACTERIA	80	Clostridium difficile
BACTERIA	85	Corynebacterium sp.
BACTERIA	90	Diphtheroids
BACTERIA	95	Eikenella sp.
BACTERIA	100	Enterobacter sp.
BACTERIA	105	Enterococcus sp.
BACTERIA	110	Escherichia coli
BACTERIA	115	Fusobacterium sp.
BACTERIA	120	Gemella sp.
BACTERIA	125	Granulicatella sp.
BACTERIA	130	Haemophilus sp.
BACTERIA	135	Haemophilus influenzae
BACTERIA	140	Hemophilus vaginalis
BACTERIA	145	Herellea vaginicola
BACTERIA	150	Kingella sp.
BACTERIA	155	Klebsiella sp.
BACTERIA	160	Lactobacillus sp.
BACTERIA	165	Legionella sp.

## DES\_FORMATS

Format Name	Code Value	Code Label
BACTERIA	170	Leuconostoc sp.
BACTERIA	175	Listeria sp.
BACTERIA	180	Listeria monocytogenes
BACTERIA	185	Micrococcus sp.
BACTERIA	190	Morganella sp.
BACTERIA	195	Mycoplasma sp.
BACTERIA	200	Neisseria sp.
BACTERIA	205	Neisseria gonorrhoeae
BACTERIA	210	Neisseria meningitidis
BACTERIA	215	Nocardia sp.
BACTERIA	220	Pantoea sp.
BACTERIA	225	Pasteurella sp.
BACTERIA	230	Peptococcus sp.
BACTERIA	235	Peptostreptococcus sp.
BACTERIA	240	Propionibacterium sp.
BACTERIA	245	Proteus sp.
BACTERIA	250	Providencia sp.
BACTERIA	255	Pseudomonas sp.
BACTERIA	260	Pseudomonas aeruginosa
BACTERIA	265	Salmonella sp.
BACTERIA	270	Serratia sp.
BACTERIA	275	Shigella sp.
BACTERIA	280	Staphylococcus sp.
BACTERIA	285	Staphylococcus aureus
BACTERIA	290	Methicillin susceptible staphylococcus aureus
BACTERIA	295	Methicillin resistant staphylococcus aureus
BACTERIA	300	Staphylococcus epidermidis
BACTERIA	305	Staphylococcus sp. (coagulase negative)
BACTERIA	310	Stenotrophomonas
BACTERIA	315	Stomatococcus sp.
BACTERIA	320	Streptobacillus sp.
BACTERIA	325	Streptococcus sp.
BACTERIA	330	Streptococcus bovis
BACTERIA	335	Streptococcus viridans
BACTERIA	340	Streptococcus milleri
BACTERIA	345	Streptococcus intermedius

## DES\_FORMATS

Format Name	Code Value	Code Label
BACTERIA	350	Streptococcus anginosus
BACTERIA	355	Streptococcus Group A (pyogenes)
BACTERIA	360	Streptococcus Group B (agalactiae)
BACTERIA	365	Streptococcus Group C
BACTERIA	370	Streptococcus pneumoniae
BACTERIA	375	Streptococcus Group G
BACTERIA	380	Streptococcus sp. (alpha hemolytic)
BACTERIA	385	Treponema sp.
BACTERIA	390	Treponema pallidum (Syphilis)
BACTERIA	395	Ureaplasma urealyticum
BACTERIA	400	Ureaplasma sp.
BACTERIA	405	Yersinia enterocolitica
BACTERIA	410	Yersinia sp.
BACTERIA	999	Other
BS	1	Immunologic
BS	2	HEENT
BS	3	Respiratory
BS	4	Cardiovascular
BS	5	Gastrointestinal
BS	6	Endocrine / Metabolic
BS	7	Neurological
BS	8	Blood / Lymphatic
BS	9	Musculoskeletal
BS	10	Hepatic
BS	11	Allergic
BS	12	Surgical History
BS	13	Dermatological
BS	98	Other
BUNU	1	mmol/L
BUNU	7	mg/dL
CALCU	1	mmol/L
CALCU	6	mEq/L
CALCU	7	mg/dL
CAPSSUSP	1	Capsules or tablets
CAPSSUSP	2	Suspension
CREATU	7	mg/dL



## DES\_FORMATS

Format Name	Code Value	Code Label
CREATU	15	umol/L
DESLBST	1	In Range
DESLBST	2	Out of Range
DESLBST	3	Out of Range (CS)
DESLBST	4	No Match
DESLBST	5	Manual Verification Needed
DESLBST	6	Result Removed
DESPGNM	265173	AE_SAE
DESPGNM	265231	CLAB
DESPGNM	265177	CM
DESPGNM	265206	DM
DESPGNM	265242	DOSEPK
DESPGNM	418517	DOSEPKAD
DESPGNM	265178	DOV
DESPGNM	265179	DS
DESPGNM	265222	HLAB
DESPGNM	265183	IE
DESPGNM	265186	MH
DESPGNM	265164	OPPK
DESPGNM	265193	PE
DESPGNM	265171	PRVDRG
DESPGNM	265162	PT
DESPGNM	265199	SAECM
DESPGNM	265200	SAELAB
DESPGNM	265201	SAE_NARR
DESPGNM	265220	SOCD
DESPGNM	265211	URINE
DESPGNM	418580	URINE_2m
DESPGST	0	Not Started
DESPGST	5	Entered
DESPGST	20	Monitored
DESPGST	15	Signed
DESSUBST	0	Enrolled
DESSUBST	5	Screen Failure
DESSUBST	30	Lost to Followup
DES_QTYP	0	System Query

## DES\_FORMATS

Format Name	Code Value	Code Label
DES_QTYP	15	DM
DES_QTYP	30	CRA
DES_QTYP	35	CODING
DES_QTYP	40	SAFETY
EMPTYSTATE	99999996	Not Applicable
EMPTYSTATE	99999998	Not Done
EMPTYSTATE	99999997	Unknown
ETHNIC	1	Hispanic or Latino
ETHNIC	2	Not Hispanic or Latino
ETHNIC	3	Not Reported
ETHNIC	4	Unknown
FUNGI	500	Alternaria sp.
FUNGI	505	Aspergillus sp.
FUNGI	510	Aureobasidium sp.
FUNGI	515	Candida sp.
FUNGI	520	Candida albicans
FUNGI	525	Candida parapsilosis
FUNGI	530	Candida tropicalis
FUNGI	535	Candida krusei
FUNGI	540	Candida glabrata
FUNGI	545	Candida guilliermondii
FUNGI	550	Candida lusitaniae
FUNGI	555	Cladosporium sp.
FUNGI	560	Malassezia furfur
FUNGI	565	Rhodotorula sp.
FUNGI	570	Saccharomyces sp.
FUNGI	575	Torulopsis glabrata
FUNGI	580	Trichosporonosis beigeli
FUNGI	585	Zygomycetes sp.
FUNGI	999	Other
HCTU	9	%
HCTU	10	L/L
HGBU	11	g/dL
HGBU	12	g/L
IP	1	Clindamycin
IP	2	TMP-SMX (trimethoprim-sulfamethoxazole)

## DES\_FORMATS

Format Name	Code Value	Code Label
NCOMPLT	1	Adverse Event
NCOMPLT	2	Complete
NCOMPLT	3	Death
NCOMPLT	4	Lack of Efficacy
NCOMPLT	5	Lost to follow-up
NCOMPLT	6	Non-compliance With Study Drug
NCOMPLT	8	Physician Decision
NCOMPLT	9	Pregnancy
NCOMPLT	10	Progressive Disease
NCOMPLT	11	Protocol Violation
NCOMPLT	12	Recovery
NCOMPLT	13	Trial Screen Failure
NCOMPLT	14	Study Terminated By Sponsor
NCOMPLT	15	Technical Problem
NCOMPLT	16	Withdrew Assent
NCOMPLT	17	Study Subject Withdrawal by Parent or Guardian
NCOMPLT	18	Recurrent Disease
NCOMPLT	98	Other
NormalClinAbnormal_LIB	1	Normal
NormalClinAbnormal_LIB	2	Abnormal, not clinically significant
NormalClinAbnormal_LIB	3	Abnormal, clinically significant
NormalClinAbnormal_LIB	4	Not Done
OPPKTP	1	Bone
OPPKTP	2	Skin
OPPKTP	3	Synovial fluid
Ongoing	1	Ongoing
Outcome	1	Recovered / Resolved
Outcome	2	Recovering / Resolving
Outcome	3	Not recovered / Not resolved
Outcome	4	Recovered / Resolved with sequelae
Outcome	5	Fatal
Outcome	99999999	Unknown
PARASITES	800	Giardia lamblia
PARASITES	805	Toxoplasma gondii
PARASITES	999	Other
PLTCU_5M	8	$\times 10^9/L$

## DES\_FORMATS

Format Name	Code Value	Code Label
PLTCU_5M	4	/mm <sup>3</sup>
PLTCU_5M	18	x10 <sup>3</sup> /μL
POSNEG	1	Positive
POSNEG	2	Negative
POTU	1	mmol/L
POTU	6	mEq/L
POTU	7	mg/dL
PRVDGNU	1	1
PRVDGNU	2	2
PRVDGNU	3	3
PRVDGNU	4	4
PRVDGNU	5	5
PRVDGNU	6	6 or more
PRVDRG	1	No
PRVDRG	2	Yes, patient received clindamycin.
PRVDRG	3	Yes, patient received TMP-SMX.
REASON_6M	1	Patient completed the study
REASON_6M	3	Patient discharged
REASON_6M	2	Other
RELATIONSHIP	1	Not related
RELATIONSHIP	2	Unlikely related
RELATIONSHIP	3	Possibly related
RELATIONSHIP	4	Related
Route	1	IV
Route	2	PO
SEVER	1	Mild
SEVER	2	Moderate
SEVER	3	Severe
SODU	1	mmol/L
SODU	6	mEq/L
SODU	7	mg/dL
SPECIES	1	Bacteria
SPECIES	2	Fungi
SPECIES	3	Viruses
SPECIES	4	Parasites
TOTBILU	7	mg/dL

## DES\_FORMATS

Format Name	Code Value	Code Label
TOTBILU	3	umol/L
TOTBILU	15	mcmol/L
TYPE	1	Blood culture
TYPE	2	Urine culture (cath/clean catch only)
TYPE	3	Cerebrospinal fluid culture (CSF)
UNIT	1	appl
UNIT	2	caps
UNIT	3	ug/kg
UNIT	4	gtts
UNIT	5	gram
UNIT	6	inj
UNIT	7	mcg
UNIT	8	mEq
UNIT	9	mg
UNIT	10	mg/kg
UNIT	11	mL
UNIT	12	ng
UNIT	13	puff
UNIT	14	oz
UNIT	15	tabs
UNIT	16	tsp
UNIT	17	units
UNIT	18	spray
UNIT	19	tbsp
VIRUSES	600	Adenovirus
VIRUSES	605	CMV
VIRUSES	610	Coxsackie
VIRUSES	615	Enterovirus
VIRUSES	620	Hepatitis A
VIRUSES	625	Hepatitis B
VIRUSES	630	Hepatitis C
VIRUSES	635	Herpes simplex virus
VIRUSES	640	HIV
VIRUSES	645	Human metapneumovirus
VIRUSES	650	Influenza A virus
VIRUSES	655	Influenza B virus

## DES\_FORMATS

Format Name	Code Value	Code Label
VIRUSES	660	Lymphocytic Choriomeningitis Virus
VIRUSES	665	Rubella
VIRUSES	670	Parainfluenza
VIRUSES	675	Rhinovirus
VIRUSES	680	RSV
VIRUSES	685	Rotavirus
VIRUSES	690	Varicella zoster virus
VIRUSES	999	Other
WBCU	1	x10 <sup>9</sup> /L
WBCU	2	/mm <sup>3</sup>
YESNO	1	Yes
YESNO	0	No
YN	1	Yes
YN	0	No
YNNA	1	Yes
YNNA	2	No
YNNA	99999996	Not Applicable
YesNo	1	Yes
YesNo	0	No
YesNoSAE	1	Yes, narrative finished
YesNoSAE	0	No, adding another narrative page
YesNo_LIB	1	Yes
YesNo_LIB	0	No
\$DESQS	0_0	Open
\$DESQS	0_5	Answered
\$DESQS	0_10	Closed
\$DESQS	15_0	Open
\$DESQS	15_5	Answered
\$DESQS	15_10	Closed
\$DESQS	30_0	Open
\$DESQS	30_5	Answered
\$DESQS	30_10	Closed
\$DESQS	35_0	Open
\$DESQS	35_5	Answered
\$DESQS	35_10	Closed
\$DESQS	40_0	Open

## DES\_FORMATS

Format Name	Code Value	Code Label
\$DESQS	40_5	Answered
\$DESQS	40_10	Closed
\$EMPTYSTATE	99999996	Not Applicable
\$EMPTYSTATE	99999998	Not Done
\$EMPTYSTATE	99999997	Unknown
\$LABMASTER	BUN	Blood Urea Nitrogen (BUN)
\$LABMASTER	CRT	Serum Creatinine
\$LABMASTER	CA	Calcium
\$LABMASTER	NA	Sodium
\$LABMASTER	K	Potassium
\$LABMASTER	AST	Aspartate Aminotransferase (AST)
\$LABMASTER	ALT	Alanine Aminotransferase (ALT)
\$LABMASTER	TBL	Total Bilirubin
\$LABMASTER	DBL	Direct Bilirubin
\$LABMASTER	ALP	Alkaline Phosphatase
\$LABMASTER	ALB	Albumin
\$LABMASTER	HGB	Hemoglobin
\$LABMASTER	HCT	Hematocrit
\$LABMASTER	PLT	Platelet Count
\$LABMASTER	WBC	White Blood Cell Count
\$LBTEST	ALT	Alanine Aminotransferase (ALT)
\$LBTEST	ALB	Albumin
\$LBTEST	AP	Alkaline Phosphatase (AP)
\$LBTEST	AMYLASE	Amylase
\$LBTEST	AST	Aspartate Aminotransferase (AST)
\$LBTEST	BILI	Bilirubin (Total)
\$LBTEST	BILICJ	Bilirubin (Conjugated)
\$LBTEST	BUN	Blood Urea Nitrogen (BUN)
\$LBTEST	CA	Calcium
\$LBTEST	CL	Chloride
\$LBTEST	CHOL	Cholesterol (total)
\$LBTEST	CREAT	Creatinine
\$LBTEST	GLUC	Glucose
\$LBTEST	LIP	Lipase
\$LBTEST	PHOS	Phosphate
\$LBTEST	K	Potassium

## DES\_FORMATS

Format Name	Code Value	Code Label
\$LBTEST	NA	Sodium
\$LBTEST	TP	Total Protein
\$LBTEST	UA	Uric Acid
\$LBTEST	HGB	Hemoglobin
\$LBTEST	HCT	Hematocrit
\$LBTEST	MCH	Mean Corpuscular Hemoglobin (MCH)
\$LBTEST	MCHC	Mean Corpuscular Hemoglobin Concentration (MCHC)
\$LBTEST	MCV	Mean Corpuscular Volume (MCV)
\$LBTEST	PLAT	Platelet Count
\$LBTEST	RBC	Red Blood Cell (RBC) Count
\$LBTEST	WBC	White Blood Cell (WBC) Count
\$LBTEST	LYM	Lymphocytes
\$LBTEST	MONO	Monocytes
\$LBTEST	BASO	Basophils
\$LBTEST	EOS	Eosinophils
\$LBTEST	NEUT	Neutrophils
\$LBTEST	CAST	Casts
\$LBTEST	KET	Ketone
\$LBTEST	NIT	Nitrite
\$LBTEST	PH	pH
\$LBTEST	PROT	Protein
\$LBTEST	CRYS	Crystals
\$LBTEST	SPG	Specific Gravity
\$LBTEST	URO	Urobilinogen
\$LBTEST	BACT	Bacteria
\$LBTEST	RBCM	RBC Microscopy
\$LBTEST	WBCM	WBC Microscopy
\$LBTEST	EPCEL	Epithelial Cells
\$LBTEST	OTHER	Other
\$SEX	M	Male
\$SEX	F	Female
\$SEXMASTER	M	Male
\$SEXMASTER	F	Female
\$UNITMASTER	LBU01	mmol/L
\$UNITMASTER	LBU02	U/L
\$UNITMASTER	LBU03	μmol/L



## DES\_FORMATS

Format Name	Code Value	Code Label
\$UNITMASTER	LBU04	/mm <sup>3</sup>
\$UNITMASTER	LBU05	IU/L
\$UNITMASTER	LBU06	mEq/L
\$UNITMASTER	LBU07	mg/dL
\$UNITMASTER	LBU08	x10 <sup>9</sup> /L
\$UNITMASTER	LBU09	%
\$UNITMASTER	LBU10	L/L
\$UNITMASTER	LBU11	g/dL
\$UNITMASTER	LBU12	g/L
\$UNITMASTER	LBU13	IU/L or U/L or mIU/mL
\$UNITMASTER	LBU14	ukat/L
\$UNITMASTER	LBU15	mcmol/L
\$UNITMASTER	LBU16	nkat/L
\$UNITMASTER	LBU17	mmol/mol
\$UNITMASTER	LBU18	x10 <sup>3</sup> /μL

## CLINDAMYCIN\_AAG

Variable	Type	Label	Format	Redacted
DEIDNUM	Num	Deidentified subject id		
SAMPLE_NUM	Char	Sample Number		
AAG_CONCENTRATION	Char	AAG Concentration ( $\mu\text{g}/\text{mL}$ )		

## CLINDAMYCIN\_PLASMA\_FINAL

Variable	Type	Label	Format	Redacted
DEIDNUM	Num	Deidentified subject id		
SAMPLE_NUM	Char	Sample Number		
CLINDAMYCIN_ CONCENTRATION	Char	Clindamycin Concentration (ng/mL)		

## CLINDAMYCIN\_PLASMA\_INTERIM

Variable	Type	Label	Format	Redacted
DEIDNUM	Num	Deidentified subject id		
RUN	Num	Run		
SAMPLE_NUM	Char	Sample Number		
CONCENTRATION	Char	Conc.		

## CLINDAMYCIN\_URINE

Variable	Type	Label	Format	Redacted
DEIDNUM	Num	Deidentified subject id		
SAMPLE_NUM	Char	Sample Number		
CLINDAMYCIN_ CONCENTRATION	Char	Clindamycin Concentration (ng/mL)		

## TMP\_SMX\_PLASMA

<b>Variable</b>	<b>Type</b>	<b>Label</b>	<b>Format</b>	<b>Redacted</b>
DEIDNUM	Num	Deidentified subject id		
SAMPLE_NUM	Char	Sample Number		
TMP_CONCENTRATION	Char	TMP Concentration (ng/mL)		
SMX_CONCENTRATION	Char	SMX Concentration (ng/mL)		

## TMP\_SMX\_URINE

<b>Variable</b>	<b>Type</b>	<b>Label</b>	<b>Format</b>	<b>Redacted</b>
DEIDNUM	Num	Deidentified subject id		
SAMPLE_NUM	Char	Sample Number		
TMP_CONCENTRATION	Char	TMP Concentration (ng/mL)		
SMX_CONCENTRATION	Char	SMX Concentration (ng/mL)		