

Clinical Development

Levofloxacin

NCT00210886

Anonymisation Data Derivation Specification Document

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Table of contents

Clinical Development	1
1. Datasets	5
1.1. Specifications Introduction	5
1.2. Guidelines for Preparing Data.....	5
1.3. Data Files.....	6
1.4. Data Domains.....	7
1.4.1. SDemographics – DEMO	7
1.4.2. ADVERSE EVENTS – ADVE	10
1.4.3. CONCOMITANT ANTIBACTERIAL THERAPY – ANTI	13
1.4.4. CENTRAL/LOCAL LAB BLOOD CULTURES – BCUL	16
1.4.5. CATHETER HISTORY AND USE – CATHHX	19
1.4.6. CATHETER INFORMATION – CATHINFO	21
1.4.7. CLINICAL RESPONSE – CLINRESP	23
1.4.8. COMMENT – CMNT.....	25
1.4.9. CONCOMITANT MEDICATIONS – CONMED	26
1.4.10. SUBJECT DIARY INFORMATION – DIARINFO	29
1.4.11. SUBJECT DIARY / QUALITY OF LIFE – DIARY	31
1.4.12. DIPSTICK_MICRO EXAM – DIPTTEST	33
1.4.13. DISCONTINUATION OF STUDY MEDICATION – DISC.....	35
1.4.14. DRUG ACCOUNTABILITY – DRUG	37
1.4.15. EXCLUSION CRITERIA – EXCL.....	39
1.4.16. EXCEPTIONS – EXCPT	44
1.4.17. COMPLICATING FACTORS – FACTORS.....	46
1.4.18. HOSPITALIZATION – HOSP	49
1.4.19. INCLUSION CRITERIA – INCL.....	51
1.4.20. DERIVED KEY SUBJECT INFORMATION – KEY.....	54
1.4.21. KEY STUDY MEDICATION INFORMATION – KEYSMED	61
1.4.22. MICRO LABS FOR PATHOGENS – KEYTYP	64
1.4.23. LOCAL LAB COLLECTION – LCUL.....	70

1.4.24.	PERTINENT MEDICAL HISTORY – MHAB	73
1.4.25.	MARKEDLY ABNORMAL LABS – MLAB	75
1.4.26.	MARKEDLY ABNORMAL LAB BASE – MLABBASE.....	78
1.4.27.	CENTRAL LAB OTHER LABS – OLAB	81
1.4.28.	HEALTH OUTCOME QUESTIONNAIRE – OUTCOME	84
1.4.29.	PERTINENT PHYSICAL EXAM – PHYS	87
1.4.30.	ORAL (PO) STUDY MEDICATION LABELS – POLABEL.....	89
1.4.31.	POST ELIGIBILITY – POSTELIG	91
1.4.32.	URINE PREGNANCY TEST – PREG	92
1.4.33.	RANDOMIZATION FILE – RANDOM.....	94
1.4.34.	RISK ASSESSMENT – RISK	96
1.4.35.	RANDOMIZATION INFORMATION – RNDM.....	98
1.4.36.	SUBJECT ROSTER – ROSTER.....	100
1.4.37.	URINARY SIGNS – SIGN	101
1.4.38.	CENTRAL LAB STANDARD LABS – SLAB	103
1.4.39.	STUDY MEDICATION – SMED	106
1.4.40.	SUPERINFECTION – SUBA.....	108
1.4.41.	SUBSTANCE ABUSE HISTORY – SUBABUSE	111
1.4.42.	SUBJECT LOG – SUBLOG.....	113
1.4.43.	COLONIZATION_PARTICIPATION SUB_STUDY – SUBSTUDY	116
1.4.44.	URINARY SYMPTOMS – SYMP	118
1.4.45.	CENTRAL LAB URINE CULTURES– UCUL.....	120
1.4.46.	UNBLINDING – UNBLIND.....	123
1.4.47.	VITAL SIGNS – VITALS.....	125

Status and Version	Release Date	Summary of Key Changes

1. Datasets

1.1. Specifications Introduction

This specification for each dataset will be in two parts

- Dataset description
- Variables within dataset

Part I: Dataset description

Dataset	Name of dataset
Creating Program	The program that created the dataset
Description	Short description
Unique Identifier	Unique key
Sorted by	Sort key
Notes	Any useful notes

Part II: Variables within dataset

Variable	SAS variable name
Type	Character or Numeric
Label	SAS variable label
Codes	Codelist name
Comments	Variable source derivation explanation if variable derived.

1.2. Guidelines for Preparing Data

The data will be provided according to the De-identified/ Anonymisation data guidelines standards with the following exceptions:

- Subject initials will not be provided
- Investigator Name will not be provided.
- Date of birth will not be provided, only age in years and grouped to protect PII as per HIPAA rules (ages above 89 will be assigned to 90+).
- Subject and site/ Investigator unique numbers will be assigned in a random manner so they are not matching the subject and site/ Investigator unique numbers that were used in the actual trial.
- Remove the free text verbatim terms.
- Remove "Other" free text terms.
- Drug Record Number will not be provided.
- Drug Sequence Number will not be provided.
- Accession Number will not be provided.
- Vial, Bottle, lot, kit number will not be provided.
- Central Lab Specimen Label Number will not be provided.

- Lab Identifier information will not be provided.
- Vendor Panel Comments will not be provided.
- Vendor Test Specific Comments will not be provided.
- Lab Name information will not be provided.
- All original dates relating to individuals subject will be removed. Instead a Relative study day would be provided.
- Complete missing value variables will be removed.
- Partial date's relative day cannot be calculated.
- Screen failure data will be removed from all domains, which has no impact on secondary analysis.
- Dataset used for data reconciliation will not be submitted. (Eg. CLABS,PATIENTS)
- NLAB will not be submitted as no subject level data present.
- INVSIG will not be submitted as it contains Investigator's signature related information, this will not be significant for analysis.
- IVLABEL will not be submitted as it contains IV medication label related information, this will not be significant for analysis.

1.3. Data Files

The NCT00210886 Clinical Study Report (CSR) data should be used for converting to de-identification.

1.4. Data Domains

1.4.1. SDemographics – DEMO

Dataset	DEMO
Creating program	demo.sas
Description	Subjects demographics information.
Unique identifier	DUNQSUB
Sorted by	DUNQSUB
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due missing values: SUBINI,PAGE,PAGEID,NOTDONE,VDATEDT,BIRTH,BIRTHF,BIRTHDT, RACESPEC,LASTNAME,INVNAME, VDATE, STOP, START, STRTSTDY, STOPSTDY, VDATEF, STRTFLAG, RACE, SEX

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
PERIOD	num	Study period code		Collected at CRF.

Variable	Type	Label	Codes	Comments
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
PERIODF	char	Study period description		Collected at CRF.
SEXF	char	Decode:gender		Collected at CRF.
RACEF	char	Decode:race		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
AGE	char	Age		Element will be grouped to protect subject PII as per HIPPA rules: If age is greater than 89 then "90+".
VDY	num	Relative Visit Day		If VDATE and REFERENCE DATE not missing then perform below logic to calculate , If VDATE less than REFERENCE DATE then (VDATE - REFERENCE DATE). Else if VDATE is greater than equal to REFERENCE DATE then (VDATE- REFERENCE DATE) +1.
STOPADY	num	Relative Active drug stop Day		If STOP and REFERENCE DATE not missing then perform below logic to calculate , If STOP less than REFERENCE DATE then (STOP - REFERENCE DATE). Else if STOP is greater than equal to REFERENCE DATE then (STOP- REFERENCE DATE) +1.

Variable	Type	Label	Codes	Comments
STARTDY	num	Relative Medication active start Day		If START and REFERENCE DATE not missing then perform below logic to calculate , If START less than REFERENCE DATE then (START - REFERENCE DATE). Else if START is greater than equal to REFERENCE DATE then (START- REFERENCE DATE) +1.
STOPSTDY	num	Relative Last study drug Day taken		If STOPSTDY and REFERENCE DATE not missing then perform below logic to calculate , If STOPSTDY less than REFERENCE DATE then (STOPSTDY - REFERENCE DATE). Else if STOPSTDY is greater than equal to REFERENCE DATE then (STOPSTDY- REFERENCE DATE) +1.

1.4.2.ADVERSE EVENTS – ADVE

Dataset	ADVE
Creating program	adve.sas
Description	ADVERSE EVENTS
Unique identifier	DUNQSUB,SEQNUM,PTERM
Sorted by	DUNQSUB,SEQNUM,PTERM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due missing values or due to non significant elements: SUBINI,PAGE,PAGEID,NOTDONE,ADVSP,ADVSEV,AESTRTDT,SAECODE, SERIOUS,ADVREL,ACTION,ADVCON,RESULT,AESTOPDT,COMMENT, LASTNAME,INVNAME, DONSET, AESTOP, DONSETF,STRFLAG,AESTOPF,STOP, START, STRTSTDY, STOPSTDY

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
PERIOD	num	Study period code		Collected at CRF.

Variable	Type	Label	Codes	Comments
PERIODF	char	Study period description		Collected at CRF.
SEQNUM	num	Sequence number		Collected at CRF.
ADVEXP	num	1=No adverse events		Collected at CRF.
ADVSEVF	char	Decode:ae severity		Collected at CRF.
SAECODEF	char	Decode:Serious ae code		Collected at CRF.
SERIOUSF	char	Decode:Serious ae		Collected at CRF.
ADVRELF	char	Decode:ae relat to study drug		Collected at CRF.
ACTIONF	char	Decode:action taken		Collected at CRF.
ADVCONF	char	Decode:concom therapy		Collected at CRF.
RESULTF	char	Decode:ae outcome		Collected at CRF.
ADVCODE	char	Ae dictionary code		Collected at CRF.
BODYSYS	char	Ae dictionary body system code		Collected at CRF.
BODYDESC	char	Ae dictionary body system descrip		Collected at CRF.
STERM	char	Ae dictionary secondary term		Collected at CRF.
PTERM	char	Ae dictionary primary term		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity

Variable	Type	Label	Codes	Comments
AEDUR	num	Duration of ae		Collected at CRF.
DAYSTRT	num	Start day of ae atart		Collected at CRF.
DAYSTOP	num	Stop day of ae atart		Collected at CRF.
PRELSTRT	num	Day rel last day of active study drug		Collected at CRF.
RAEDAY	char	Start day of ae relative to pt		Collected at CRF.
TREATEMR	char	Treatment emergent ae flag (Y/N)		Collected at CRF.
MAXSEV	num	Max severity for t-e ae		Collected at CRF.
MAXREL	num	Max relat to study drug for t-e ae		Collected at CRF.
DONSETDY	num	Relative Ae onset day		If DONSET and REFERENCE DATE not missing then perform below logic to calculate , If DONSET less than REFERENCE DATE then (DONSET - REFERENCE DATE). Else if DONSET is greater than equal to REFERENCE DATE then (DONSET- REFERENCE DATE) +1.
AESTOPDY	num	Relative Ae Stop day		If AESTOP and REFERENCE DATE not missing then perform below logic to calculate , If AESTOP less than REFERENCE DATE then (AESTOP - REFERENCE DATE). Else if AESTOP is greater than equal to REFERENCE DATE then (AESTOP- REFERENCE DATE) +1.

1.4.3. CONCOMITANT ANTIBACTERIAL THERAPY – ANTI

Dataset	ANTI
Creating program	anti.sas
Description	CONCOMITANT ANTIBACTERIAL THERAPY
Unique identifier	DUNQSUB,FREQ,PERIOD,ATC_CODE,DRUGCODE
Sorted by	DUNQSUB,FREQ,PERIOD,ATC_CODE,DRUGCODE
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due missing values or due to non significant elements : SUBINI,PAGE,PAGEID,VERBATIM,INDICAT,NOTDONE,LASTNAME,INVNAME,ASTARTDT,ASTOPDT,FLAG, STOP, STARTDT, STOPDT, START, STRTSTDY, STOPSTDY, STARTDTF, STOPDTF, STRTFLAG, RTOTH

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
PERIOD	num	Study period code		Collected at CRF.
PERIODF	char	Period description		Collected at CRF.

Variable	Type	Label	Codes	Comments
ANTIMED	num	1=No concurrent antimicrobial taken		Collected at CRF.
DOSE	char	Dose		Collected at CRF.
UNIT	char	Unit		Collected at CRF.
FREQ	char	Frequency		Collected at CRF.
RT	num	Route		Collected at CRF.
RTF	char	Decode:route		Collected at CRF.
CONT	num	1=continuing		Collected at CRF.
TOTDOSE	char	Total no. doses taken		Collected at CRF.
DRUGCODE	char	Who dictionary for drug		Collected at CRF.
ECT	char	Effective anti med (N/Y)		Collected at CRF.
IND	char	Indication - Antimed(U=UTI,A=AP,O=Other)		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
DRUGDESC	char	Dictionary drug name		Collected at CRF.
ATC_CODE	char	Dictionary code for drug		Collected at CRF.
ATC_TEXT	char	Dictionary text for drug		Collected at CRF.

Variable	Type	Label	Codes	Comments
THER	char	Dict therapeutic class for drug		Collected at CRF.
PHARM	char	Dict pharmacological class for drug		Collected at CRF.
GEN_NAME	char	Generic name		Collected at CRF.
FLAGF	char	Decode:2=antimicrobial drug flag		Collected at CRF.
ANSTRDY	num	Anti med start day:(astartdt-start)+1		Collected at CRF.
ANSTOPDY	num	Anti med stop day:(astopdt-start)+1		Collected at CRF.
STARTDY	num	Relative Anti med start Day		If STARTDT and REFERENCE DATE not missing then perform below logic to calculate STARTDY, If STARTDT less than REFERENCE DATE then (STARTDT - REFERENCE DATE). Else if STARTDT is greater than equal to REFERENCE DATE then (STARTDT- REFERENCE DATE) +1.
STOPDY	num	Relative Anti med stop Day		If STOPDT and REFERENCE DATE not missing then perform below logic to calculate STOPDY, If STOPDT less than REFERENCE DATE then (STOPDT - REFERENCE DATE). Else if STOPDT is greater than equal to REFERENCE DATE then (STOPDT- REFERENCE DATE) +1.

1.4.4.CENTRAL/LOCAL LAB BLOOD CULTURES – BCUL

Dataset	BCUL
Creating program	bcul.sas
Description	CENTRAL/LOCAL LAB BLOOD CULTURES
Unique identifier	DUNQSUB,VDY,CULTNUM
Sorted by	DUNQSUB,VDY,CULTNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements: SUBINI,PAGE,PAGEID,VDATEDT,SOURCE,VERBATIM,PATH,LASTNAME, INVNAME, SPECDT,VDATE, SPECDATE, STOP, START, STRTSTDY, STOPSTDY, VDATEF, SPECDATEF,STRFLAG

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study Protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
PERIOD	num	Study Period code		Collected at CRF.
PERIODF	char	Study Period description		Collected at CRF.

Variable	Type	Label	Codes	Comments
SOURCEF	char	Decode:source of culture (blood)		Collected at CRF.
CULTNUM	num	Blood culture number		Collected at CRF.
CULTNO	num	Culture number		Collected at CRF.
PATHF	char	Decode: pathogen code		Collected at CRF.
P_ECT	char	Effective concomitant therapy-pathogen		Collected at CRF.
FULLINF	char	Infect dictionary code		Collected at CRF.
DRUG	char	Decode:drug code		Collected at CRF.
DRUGCODE	char	ECT drug code - who drug dictionary		Collected at CRF.
INFDESC	char	Decode:fullinf		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
LAB	num	Lab (1-central,2-local)		Collected at CRF.
LABF	char	Decode:lab		Collected at CRF.

Variable	Type	Label	Codes	Comments
VDY	num	Relative Visit Day		If VDATE and REFERENCE DATE not missing then perform below logic to calculate , If VDATE less than REFERENCE DATE then (VDATE - REFERENCE DATE). Else if VDATE is greater than equal to REFERENCE DATE then (VDATE- REFERENCE DATE) +1.
SPEC DY	num	Relative Specimen culture Day		If SPECDATE and REFERENCE DATE not missing then perform below logic to calculate , If SPECDATE less than REFERENCE DATE then (SPECDATE - REFERENCE DATE). Else if SPECDATE is greater than equal to REFERENCE DATE then (SPECDATE- REFERENCE DATE) +1.

1.4.5.CATHETER HISTORY AND USE – CATHHX

Dataset	CATHHX
Creating program	cathhx.sas
Description	CATHETER HISTORY AND USE
Unique identifier	DUNQSUB
Sorted by	DUNQSUB
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements: SUBINI,PAGE,PAGEID,VDATEDT,CATHHX4,CATHHX5,CATHHX6,LASTNAME, INVNAME, VDATE, STOP, START,STRTSTDY ,STOPSTDY, VDATEF, CATHHX1, CATHHX2, CATHHX3, STRTFLAG, CATHHX6Y

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
PERIOD	num	Study period code		Collected at CRF.
PERIODF	char	Study period description		Collected at CRF.

Variable	Type	Label	Codes	Comments
NOTDONE	num	Page not done (-6)		Collected at CRF.
CATHHX4F	char	Decode:inter. st. cat use(ster/clean)		Collected at CRF.
CATHHX5F	char	Decode:other type cath-condom		Collected at CRF.
CATHX6YF	char	Decode:other type catheter		Collected at CRF.
NA	num	Section not applicable		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
VDY	num	Relative Visit Day		If VDATE and REFERENCE DATE not missing then perform below logic to calculate , If VDATE less than REFERENCE DATE then (VDATE - REFERENCE DATE). Else if VDATE is greater than equal to REFERENCE DATE then (VDATE- REFERENCE DATE) +1.

1.4.6.CATHETER INFORMATION – CATHINFO

Dataset	CATHINFO
Creating program	cathinfo.sas
Description	CATHETER INFORMATION
Unique identifier	DUNQSUB,PERIOD,VDY,RPT,CATHCHNF,SAMPF
Sorted by	DUNQSUB,PERIOD,VDY,RPT,CATHCHNF,SAMPF
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements: SUBINI,PAGE,PAGEID,VDATEDT,CATHPRES,CATHCHNG,EXPLAIN,SAMPSPEC, LASTNAME,INVNAME, VDATE, STOP, START,STRSTDY ,STOPSTDY, STRTFLAG, VDATEF, SAMP

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study Protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
RPT	char	Repeated/Unscheduled Visit (R)		Collected at CRF.

Variable	Type	Label	Codes	Comments
PERIOD	num	Study Period code		Collected at CRF.
PERIODF	char	Study Period description		Collected at CRF.
NOTDONE	num	Page not done (-6=Not done)		Collected at CRF.
CATHPREF	char	Decode:Cathpres		Collected at CRF.
CATHCHNF	char	Decode:cathchng		Collected at CRF.
ND	num	Catheter change not done		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
SAMPF	char	Decode:samp		Collected at CRF.
VDY	num	Relative Visit Day		If VDATE and REFERENCE DATE not missing then perform below logic to calculate , If VDATE less than REFERENCE DATE then (VDATE - REFERENCE DATE). Else if VDATE is greater than equal to REFERENCE DATE then (VDATE- REFERENCE DATE) +1.

1.4.7. CLINICAL RESPONSE – CLINRESP

Dataset	CLINRESP
Creating program	clinresp.sas
Description	CLINICAL RESPONSE
Unique identifier	DUNQSUB,PERIOD
Sorted by	DUNQSUB,PERIOD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to non significant elements: SUBINI,PAGE,PAGEID,VDATEDT,LASTNAME,INVNAME, VDATE, STOP, START,STRSTDY ,STOPSTDY, VDATEF, STRTFLAG

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number assigned for De-identity for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
PERIOD	num	Study period code		Collected at CRF.
PERIODF	char	Study period description		Collected at CRF.

Variable	Type	Label	Codes	Comments
NOTDONE	num	Page not done (-6=Not done)		Collected at CRF.
ND	num	ND		Collected at CRF.
CLINRES	num	Clin resp(1=c,2=i,3=f,4=u,5=lt f)		Collected at CRF.
CLINRESF	char	Decode:clinical response		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
VDY	num	Relative Visit Day		If VDATE and REFERENCE DATE not missing then perform below logic to calculate , If VDATE less than REFERENCE DATE then (VDATE - REFERENCE DATE). Else if VDATE is greater than equal to REFERENCE DATE then (VDATE- REFERENCE DATE) +1.

1.4.8.COMMENT – CMNT

Dataset	CMNT
Creating program	cmnt.sas
Description	COMMENT
Unique identifier	
Sorted by	
Notes	Comments data is sensitive data, contains free text information. Empty dataset will be submitted.

Variable	Type	Label	Codes	Comments
DSUBNUM	num	Subject number assign for De-identity		Randomly assigned Subject number assign for De-identity for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
PERIOD	num	Study period code		Collected at CRF.
PERIODF	char	Study period description		Collected at CRF.
CMNTID	num	CMNTID		Collected at CRF.
TABLE	char	Dataset table name		Collected at CRF.
FORM	char	Comment source		Collected at CRF.
SEQ	num	Seq		Collected at CRF.

Variable	Type	Label	Codes	Comments
MODULE	char	Module		Collected at CRF.
CMNTCODE	char	Comment source abbreviation		Collected at CRF.

1.4.9. CONCOMITANT MEDICATIONS – CONMED

Dataset	CONMED
Creating program	conmed.sas
Description	CONCOMITANT MEDICATIONS
Unique identifier	DUNQSUB,DRUGCODE,SEQNUM,FREQ
Sorted by	DUNQSUB,DRUGCODE,SEQNUM,FREQ
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due missing values or due to non significant elements: SUBINI,PAGE,PAGEID,NOTDONE,STARTDT,ASTARTDT,STOPDT,ASTOPDT,VERBATIM,INDICAT,RTOTH,LASTNAME,INVNAME,STOP,START,STRTSTDY,STOPSTDY, STARTDTF, STOPDTF, STRTFLAG

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.

Variable	Type	Label	Codes	Comments
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
PERIOD	num	Study period code		Collected at CRF.
PERIODF	char	Decode:period		Collected at CRF.
CONMED	num	1=No concomitant medication		Collected at CRF.
ASTRTDY	num	Con med start day:(startdt-start)+1		Collected at CRF.
ASTOPDY	num	Con med stop day:(stopdt-start)+1		Collected at CRF.
CONT	num	1=continuing		Collected at CRF.
SEQNUM	num	Sequence number		Collected at CRF.
ATC_CODE	char	Dictionary code for drugdesc		Collected at CRF.
ATC_TEXT	char	Dictionary text for drugdesc		Collected at CRF.
DRUGCODE	char	Who dictionary drugdesc code		Collected at CRF.
DRUGDESC	char	Dictionary drugdesc name		Collected at CRF.
GEN_NAME	char	Generic name		Collected at CRF.
PHARM	char	Dict pharmacological class drugdesc		Collected at CRF.
THER	char	Dict therapeutic class for drugdesc		Collected at CRF.
FLAG	num	Type of concomitant medication		Collected at CRF.

Variable	Type	Label	Codes	Comments
FLAGF	char	Decode:type of concomitant med		Collected at CRF.
DRGPRIOR	num	Drug taken prior study meds(1-N/2-Y)		Collected at CRF.
DXREL	num	Diagnosis related(1)		Collected at CRF.
DOSE	char	Dose		Collected at CRF.
UNIT	char	Units		Collected at CRF.
FREQ	char	Frequency		Collected at CRF.
RT	num	Route		Collected at CRF.
RTF	char	Decode:route		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity

1.4.10. SUBJECT DIARY INFORMATION – DIARINFO

Dataset	DIARINFO
Creating program	diarinfo.sas
Description	SUBJECT DIARY INFORMATION
Unique identifier	DUNQSUB
Sorted by	DUNQSUB
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due missing values or due to non significant elements: SUBINI,PAGE,PAGEID,NOTDONE,DISDT,RETDT,LASTNAME,INVNAME, DISDATE, RETDATE, STOP, START,STRTSTDY ,STOPSTDY, DISDATEF, RETDATEF, STRTFLAG

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
PERIOD	num	Study period code		Collected at CRF.
PERIODF	char	Study period description		Collected at CRF.

Variable	Type	Label	Codes	Comments
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
DISDATDY	num	Relative Dispensed Day		If DISDATE and REFERENCE DATE not missing then perform below logic to calculate , If DISDATE less than REFERENCE DATE then (DISDATE - REFERENCE DATE). Else if DISDATE is greater than equal to REFERENCE DATE then (DISDATE- REFERENCE DATE) +1.
RETDATDY	num	Relative Returned Day		If RETDATE and REFERENCE DATE not missing then perform below logic to calculate , If RETDATE less than REFERENCE DATE then (RETDATE - REFERENCE DATE). Else if RETDATE is greater than equal to REFERENCE DATE then (RETDATE- REFERENCE DATE) +1.

1.4.11. SUBJECT DIARY / QUALITY OF LIFE – DIARY

Dataset	DIARY
Creating program	diary.sas
Description	SUBJECT DIARY / QUALITY OF LIFE
Unique identifier	DUNQSUB, DAYNUM, SYMPNUM
Sorted by	DUNQSUB, DAYNUM, SYMPNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due missing values or due to non significant elements: SUBINI, PAGE, PAGEID, NOTDONE, DAYDT, LASTNAME, INVNAME, DAYDATE, STOP, START, STRTSTDY, STOPSTDY, STRTFLAG, DAYDATEF, SYMPTOM

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
PERIOD	num	Study period code		Collected at CRF.
PERIODF	char	Study period description		Collected at CRF.

Variable	Type	Label	Codes	Comments
DAYNUM	num	DAYNUM		Collected at CRF.
SYMPTOMF	char	Decode symptom		Collected at CRF.
SYMPDESC	char	Symptom description		Collected at CRF.
HRSNORM	char	No. of hours normally at school or work		Collected at CRF.
HRSMISS	char	No. hrs missed due cur cuti/AP symptoms		Collected at CRF.
RSOLVDAY	num	Resolution of time day		Collected at CRF.
CENSOR	num	1-resolv day rt-censor value;0-obs value		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
SYMPNUM	num	Symptom number		Collected at CRF.
DAYDATDY	num	Relative Day		If DAYDATE and REFERENCE DATE not missing then perform below logic to calculate , If DAYDATE less than REFERENCE DATE then (DAYDATE - REFERENCE DATE). Else if DAYDATE is greater than equal to REFERENCE DATE then (DAYDATE- REFERENCE DATE) +1.

1.4.12. DIPSTICK_MICRO EXAM – DIPTTEST

Dataset	DIPTTEST
Creating program	diptest.sas
Description	LEUKO ESTERASE DIPSTICK_MICRO EXM URINE
Unique identifier	DUNQSUB
Sorted by	DUNQSUB
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due missing or due to non significant elements: SUBINI,PAGE,PAGEID,NOTDONE,VDATEDT,DIPPERF,EXAMRES1,EXAMRES2,LA STNAME,INVNAME,VDATE,STOP,START,STRTSTDY,STOPSTDY, STRTFLAG, VDATEF, DIPRES, EXAMPERF

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
PERIOD	num	Study period code		Collected at CRF.

Variable	Type	Label	Codes	Comments
PERIODF	char	Study period description		Collected at CRF.
DIPPERFF	char	Decode:dipperf		Collected at CRF.
DIPRESF	char	Dipstick results(1=Neg/trace,2=pos)		Collected at CRF.
EXAMPRFF	char	Decode:micro exam urine done?(1=N,2=Y)		Collected at CRF.
EXAMRS1F	char	Decode:examres1		Collected at CRF.
EXAMRS2F	char	Decode:examres2		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
VDY	num	Relative Visit Day		If VDATE and REFERENCE DATE not missing then perform below logic to calculate , If VDATE less than REFERENCE DATE then (VDATE - REFERENCE DATE). Else if VDATE is greater than equal to REFERENCE DATE then (VDATE- REFERENCE DATE) +1.

1.4.13. DISCONTINUATION OF STUDY MEDICATION – DISC

Dataset	DISC
Creating program	disc.sas
Description	DISCONTINUATION OF STUDY MEDICATION
Unique identifier	DUNQSUB
Sorted by	DUNQSUB
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due missing values or due to non significant elements:</p> <p>SUBINI,PAGE,PAGEID,NOTDONE,WDATEDT,ADVSPEC,DIEDT,PROTSPEC,OTHSPEC,OTHSPEC2,LASTNAME,INVNAME,DEATH,DEATHF, WDATE, DIEDATE, STOP,START,STRTSTDY,STOPSTDY, STRTFLAG, WDATEF, DIEDATEF, STRTFLAG, DISCLAST, WITHDRAW, REAS</p>

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
PERIOD	num	Study period code		Collected at CRF.

Variable	Type	Label	Codes	Comments
PERIODF	char	Study period description		Collected at CRF.
WITHDRWF	char	Decode:withdraw/early		Collected at CRF.
RESULT	num	Did ae result in death(1=N,2=Y)		Collected at CRF.
REASF	char	Decode:Reason for early withdrawal		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
DISCLSTF	char	Decode:discont-1st dose/toc(1=N,2=Y)		Collected at CRF.
WDATEDY	num	Relative Withdrawal Day		If WDATE and REFERENCE DATE not missing then perform below logic to calculate , If WDATE less than REFERENCE DATE then (WDATE - REFERENCE DATE). Else if WDATE is greater than equal to REFERENCE DATE then (WDATE- REFERENCE DATE) +1.
DIEDATDY	num	Relative Death Day		If DIEDATE and REFERENCE DATE not missing then perform below logic to calculate , If DIEDATE less than REFERENCE DATE then (DIEDATE - REFERENCE DATE). Else if DIEDATE is greater than equal to REFERENCE DATE then (DIEDATE- REFERENCE DATE) +1.

1.4.14. DRUG ACCOUNTABILITY – DRUG

Dataset	DRUG
Creating program	drug.sas
Description	DRUG ACCOUNTABILITY
Unique identifier	DUNQSUB
Sorted by	DUNQSUB
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due missing values or due to non significant elements: SUBINI,PAGE,PAGEID,REASON,NOTDONE,LASTNAME,INVNAME,STOP,START,STRTSTDY,STOPSTDY, STRTFLAG

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
PERIOD	num	Study period code		Collected at CRF.
PERIODF	char	Study period description		Collected at CRF.
AMNUM	char	Calculated capsules remaining-am		Collected at CRF.

Variable	Type	Label	Codes	Comments
PMNUM	char	Calculated capsules remaining-pm		Collected at CRF.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity

1.4.15. EXCLUSION CRITERIA – EXCL

Dataset	EXCL
Creating program	excl.sas
Description	EXCLUSION CRITERIA
Unique identifier	DUNQSUB
Sorted by	DUNQSUB
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due missing values or due to non significant elements: SUBINI,PAGE,PAGEID,NOTDONE,VDATEDT,LASTNAME,INVNAME, VDATE, PADATE, STOP,START,STRSTDY,STOPSTDY, VDATEF, STRTFLAG

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
PERIOD	num	Study period code		Collected at CRF.
PERIODF	char	Study period description		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXCL1	num	Prev algy,sae,fail to levo (1=N,2=Y)		Collected at CRF.
EXCL2	num	Urin trct surg/litho w/7day(1=N,2=Y)		Collected at CRF.
EXCL3	num	2nd co-ex bact infect req anti(1=N,2=Y)		Collected at CRF.
EXCL4	num	Require add'L syst antibact(1=N,2=Y)		Collected at CRF.
EXCL5	num	Symptoms limited to cuti(1=N,2=Y)		Collected at CRF.
EXCL6	num	Quinoline treat infect w/30day(1=N,2=Y)		Collected at CRF.
EXCL7	num	Receipt of antibact, unless cf(1=N,2=Y)		Collected at CRF.
EXCL8	num	Resist to levo or oth quiolone(1=N,2=Y)		Collected at CRF.
EXCL9	num	Obs any portion urinary tract(1=N,2=Y)		Collected at CRF.
EXCL10	num	Need surgery for urinary tract(1=N,2=Y)		Collected at CRF.
EXCL11	num	Pres act bact prost/epid(1=N,2=Y,3=NA)		Collected at CRF.
EXCL12	num	Hist chron bact prost(1=N,2=Y,3=NA)		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXCL13	num	Hist poly kidney disease(1=N,2=Y)		Collected at CRF.
EXCL14	num	Renal transplantation(1=N,2=Y)		Collected at CRF.
EXCL15	num	One functional kidney(1=N,2=Y)		Collected at CRF.
EXCL16	num	Chr sup cat, nephr tub/cnd cat(1=N,2=Y)		Collected at CRF.
EXCL17	num	Renal/peri-renal abscess(1=N,2=Y)		Collected at CRF.
EXCL18	num	Emphy pyelonephritis/chr pyelo(1=N,2=Y)		Collected at CRF.
EXCL19	num	Ileal loop surg/vesico reflux(1=N,2=Y)		Collected at CRF.
EXCL20	num	Gross hematuria needs interven(1=N,2=Y)		Collected at CRF.
EXCL21	num	Creatinine clear <50 ml/min(1=N,2=Y)		Collected at CRF.
EXCL22	num	Life expect < 72 hrs(1=N,2=Y)		Collected at CRF.
EXCL23	num	Seizer disord/low seiz thresh(1=N,2=Y)		Collected at CRF.
EXCL24	num	Psych condition req tranquil(1=N,2=Y)		Collected at CRF.

Variable	Type	Label	Codes	Comments
EXCL25	num	Pregnancy or nursing(1=N,2=Y,3=N/A)		Collected at CRF.
EXCL26	num	Hiv inf,cur or prev cd4< 200 (1=N,2=Y)		Collected at CRF.
EXCL27	num	Presence of neutropenia(1=N,2=Y)		Collected at CRF.
EXCL28	num	Cur drug,alc abse,homeless(1=N,2=Y)		Collected at CRF.
EXCL29	num	Experiment drug w/in 30 days(1=N,2=Y)		Collected at CRF.
EXCL30	num	Use antiarrhythmic cl sia,iii(1=N,2=Y)		Collected at CRF.
EXCL31	num	Unable to complete diary(1=N,2=Y)		Collected at CRF.
EXCL32	num	Prev treated under protocol(1=N,2=Y)		Collected at CRF.
EXCL33	num	Disorder/disease inter w/eval(1=N,2=Y)		Collected at CRF.
EXCL34	num	Inv opin subj shld not enroll(1=N,2=Y)		Collected at CRF.
EXCL35	num	Employee of inv_site (1=N,2=Y)		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.

Variable	Type	Label	Codes	Comments
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
VDY	num	Relative Visit Day		If VDATE and REFERENCE DATE not missing then perform below logic to calculate , If VDATE less than REFERENCE DATE then (VDATE - REFERENCE DATE). Else if VDATE is greater than equal to REFERENCE DATE then (VDATE- REFERENCE DATE) +1.
PADATEDY	num	Relative Day prot amend implted by site		If PADATE and REFERENCE DATE not missing then perform below logic to calculate , If PADATE less than REFERENCE DATE then (PADATE - REFERENCE DATE). Else if PADATE is greater than equal to REFERENCE DATE then (PADATE- REFERENCE DATE) +1.

1.4.16. EXCEPTIONS – EXCPT

Dataset	EXCPT
Creating program	excpt.sas
Description	EXCEPTIONS APPROVED BY THE MEDICAL MONITOR
Unique identifier	DUNQSUB
Sorted by	DUNQSUB
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due missing values or due to non significant elements: SUBINI,PAGE,PAGEID,NOTDONE,VDATEDT,EXCEPTID,IENUM, MEDNAME,IEDESC,LASTNAME,INVNAME,APPDT, VDATE, APPDATE, STOP,START,STRTSTDY,STOPSTDY, VDATEF, APPDATEF, STRTFLAG

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
PERIOD	num	Study period code		Collected at CRF.
PERIODF	char	Study period description		Collected at CRF.

Variable	Type	Label	Codes	Comments
WAIVER	char	Med. mon. waiver		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
VDY	num	Relative Visit Day		If VDATE and REFERENCE DATE not missing then perform below logic to calculate , If VDATE less than REFERENCE DATE then (VDATE - REFERENCE DATE). Else if VDATE is greater than equal to REFERENCE DATE then (VDATE- REFERENCE DATE) +1.
APPDATDY	num	Relative Day apprv grant by med mon		If APPDATE and REFERENCE DATE not missing then perform below logic to calculate , If APPDATE less than REFERENCE DATE then (APPDATE - REFERENCE DATE). Else if APPDATE is greater than equal to REFERENCE DATE then (APPDATE- REFERENCE DATE) +1.

1.4.17. COMPLICATING FACTORS – FACTORS

Dataset	FACTORS
Creating program	factors.sas
Description	COMPLICATING FACTORS
Unique identifier	DUNQSUB
Sorted by	DUNQSUB
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due missing values or due to non significant elements: SUBINI,PAGE,PAGEID,NOTDONE,VDATEDT,CP1,CP1INFO1,CP1DT,CP1INFO2,CP1INFO3,CP1SPEC,CP2,CP2INFO1,CP2INFO2,CP2INFO3,CP2INFO4,P2INFO5,CP2INFO6,CP2INFO7,CP2SPEC,CP3,CP3SPEC,LASTNAME,INVNAME,VDATE,CP1DATE, STOP,START,STRTSTDY,STOPSTDY, VDATEF, STRTFLAG, CP1DATEF, CP1INFO4, CP3INFO

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity

Variable	Type	Label	Codes	Comments
PERIOD	num	Study period code		Collected at CRF.
PERIODF	char	Study period description		Collected at CRF.
CP1F	char	Decode:cp1		Collected at CRF.
CP1INF1F	char	Decode:cp1info1		Collected at CRF.
CP1MEAS	char	Nb/ut measurement		Collected at CRF.
CP1INF2F	char	Decode:cp1info2		Collected at CRF.
CP1INF3F	char	Decode:neuro bladder/urin retent:othr		Collected at CRF.
CP2F	char	Decode:cp2		Collected at CRF.
CP2INF1F	char	Decode:cp2info1		Collected at CRF.
CP2INF2F	char	Decode:cp2inco2		Collected at CRF.
CP2INF3F	char	Decode:cp2info3		Collected at CRF.
CP2INF4F	char	Decode:cp2info4		Collected at CRF.
CP2INF5F	char	Decode:cp2info5		Collected at CRF.
CP2INF6F	char	Decode:cp2info6		Collected at CRF.
CP2INF7F	char	Decode:cp2info7		Collected at CRF.
CP3F	char	Decode:cp3		Collected at CRF.
CP3INFOF	char	1=ci-non-supra,2=ci- supra,3=int/st,4=oth		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2- Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.

Variable	Type	Label	Codes	Comments
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
CP1INF4F	char	Decode:hx of noct comp w/urin retent		Collected at CRF.
VDY	num	Relative Visit Day		If VDATE and REFERENCE DATE not missing then perform below logic to calculate , If VDATE less than REFERENCE DATE then (VDATE - REFERENCE DATE). Else if VDATE is greater than equal to REFERENCE DATE then (VDATE- REFERENCE DATE) +1.
CP1DATDY		Relative Day of measurement		If CP1DATE and REFERENCE DATE not missing then perform below logic to calculate , If CP1DATE less than REFERENCE DATE then (CP1DATE - REFERENCE DATE). Else if CP1DATE is greater than equal to REFERENCE DATE then (CP1DATE - REFERENCE DATE) +1.

1.4.18. HOSPITALIZATION – HOSP

Dataset	HOSP
Creating program	Hosp.sas
Description	HOSPITALIZATION
Unique identifier	DUNQSUB
Sorted by	DUNQSUB
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due missing values or due to non significant elements: SUBINI,PAGE,PAGEID,VDATEDT,ONGOING,LASTNAME,INVNAME,ADDT,DISDT,VDATE,ADDATE,ADDATEF,DISDATE,STOP,START,STRTSTDY,STOPSTDY, VDATEF, ADDATEF, DISDATEF, STRTFLAG, PRIMDIAG

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study protocol number		Collected at CRF.
DSUBNUM	num	Subject number assign for De-identity		Randomly assigned Subject number assign for De-identity for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
PERIOD	num	Study period code		Collected at CRF.
PERIODF	char	Study period description		Collected at CRF.

Variable	Type	Label	Codes	Comments
NOTDONE	num	Page not done (-6=Not done)		Collected at CRF.
NA	num	Section not done (1)		Collected at CRF.
ONGOINGF	char	Decode:ongoing		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
VDY	num	Relative Visit Day		If VDATE and REFERENCE DATE not missing then perform below logic to calculate , If VDATE less than REFERENCE DATE then (VDATE - REFERENCE DATE). Else if VDATE is greater than equal to REFERENCE DATE then (VDATE- REFERENCE DATE) +1.
ADDEDY	num	Relative Hospital admission Day		If ADDATE and REFERENCE DATE not missing then perform below logic to calculate , If ADDATE less than REFERENCE DATE then (ADDATE - REFERENCE DATE). Else if ADDATE is greater than equal to REFERENCE DATE then (ADDATE- REFERENCE DATE) +1.
DISDATDY	num	Relative Hospital discharge Day		If DISDATE and REFERENCE DATE not missing then perform below logic to calculate , If DISDATE less than REFERENCE DATE then (DISDATE - REFERENCE DATE). Else if DISDATE is greater than equal to REFERENCE DATE then (DISDATE- REFERENCE DATE) +1.

1.4.19. INCLUSION CRITERIA – INCL

Dataset	INCL
Creating program	incl.sas
Description	INCLUSION CRITERIA
Unique identifier	DUNQSUB
Sorted by	DUNQSUB
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due missing values or due to non significant elements: SUBINI,PAGE,PAGEID,NOTDONE,VDATEDT,LASTNAME,INVNAME, CONSDT,VDATE,PADATE,CONSDATE,STOP,START,STRTSTDY,STOPSTDY, VDATEF, CONSDATF, STRTFLAG

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
PERIOD	num	Study period code		Collected at CRF.
PERIODF	char	Study period description		Collected at CRF.

Variable	Type	Label	Codes	Comments
INCL1	num	M/F,>= 18 cond of age (1=N,2=Y)		Collected at CRF.
INCL2	num	Pos dip stick/5 wbcs/10 wbcs(1=N,2=Y)		Collected at CRF.
INCL3	num	Comm/Instit based (1=N,2=Y)		Collected at CRF.
INCL4	num	AP/cuti (1=N,2=Y)		Collected at CRF.
INCL41	num	Acute pyleonephritis (1=N,2=Y)		Collected at CRF.
INCL42	num	Cuti w/chron indw Catheter (1=N,2=Y)		Collected at CRF.
INCL43	num	Cuti w/out chron indw Cath(1=N,2=Y)		Collected at CRF.
INCL5	num	If female patient (2=Y,3=N/A)		Collected at CRF.
INCL51	num	Postmenopausal > one year(1=Y)		Collected at CRF.
INCL52	num	Hysterectomy(1=Y)		Collected at CRF.
INCL53	num	Bilaster tubal ligat,incap pregn(1=Y)		Collected at CRF.
INCL54	num	Nrm mnst pat, contra, neg preg tst(1=Y)		Collected at CRF.
INCL6	num	Read and signed ic form (1=N,2=Y)		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2- Comp)		Collected at CRF.

Variable	Type	Label	Codes	Comments
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
VDY	num	Relative Visit Day		If VDATE and REFERENCE DATE not missing then perform below logic to calculate , If VDATE less than REFERENCE DATE then (VDATE - REFERENCE DATE). Else if VDATE is greater than equal to REFERENCE DATE then (VDATE- REFERENCE DATE) +1.
PADATEDY	num	Relative Day prot amend implted by site		If PADATE and REFERENCE DATE not missing then perform below logic to calculate , If PADATE less than REFERENCE DATE then (PADATE - REFERENCE DATE). Else if PADATE is greater than equal to REFERENCE DATE then (PADATE- REFERENCE DATE) +1.
CONSDADY	num	Relative Day informed consent signed		If CONSDATE and REFERENCE DATE not missing then perform below logic to calculate , If CONSDATE less than REFERENCE DATE then (CONSDATE - REFERENCE DATE). Else if CONSDATE is greater than equal to REFERENCE DATE then (CONSDATE- REFERENCE DATE) +1.

1.4.20. DERIVED KEY SUBJECT INFORMATION – KEY

Dataset	KEY
Creating program	key.sas
Description	DERIVED KEY SUBJECT INFORMATION
Unique identifier	DUNQSUB
Sorted by	DUNQSUB
Notes	<p>Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due missing values:</p> <p>SUBINI,SEX,SEXF,RACE,RACEF,RACESPEC,LASTNAME,INVNAME,AGE,ORIGSPEC,RNDMNUM,KITNUM,WITHDRAW,REAS,DIEDT,IND, BIRTHDT,ADMDATE,STOP,START,STRTSTDY,EVALDTD2,EVALDTD3,EVALDTET,EVALDTC,EVALDTPS,VDT1A, STRTFLAG, NOTRAND, STOPSTDY, STRATUM, CLINRET, CLINRES</p>

Variable	Type	Label	Codes	Comments
MMTAG	char	Medical Monitor's Micro Eval Code		Collected at CRF.
EVAL	char	Highest Eval:Micro/mITT/ITT/Safe/Unenv		Collected at CRF.
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

Variable	Type	Label	Codes	Comments
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
AGECAT	num	Age Category - numeric		Collected at CRF.
AGECATF	char	Age Category format		Collected at CRF.
ORIGIN	num	Origin of Infection		Collected at CRF.
STRATUMF	char	Decode:subject stratification		Collected at CRF.
STRATA	num	Stratum 1,2=1(AP);Strat 3,4,5,6=2(cUTI)		Collected at CRF.
ADVEXP	char	Adverse Event:N=No,Y=Yes,U=Unk,M=Miss		Collected at CRF.
SERIOUS	char	Ser Adverse Event:N=No,Y=Yes,U=Unk		Collected at CRF.
MMSTRAT	num	Med. Mon. Subject Stratification		Collected at CRF.
MM2STRAT	num	2nd Med. Mon. Subject Stratification		Collected at CRF.
REENROLL	num	Subject reenrolled in study(1)		Collected at CRF.
COMBODIF	num	Subj received iv/po trt levo/comp (1)		Collected at CRF.

Variable	Type	Label	Codes	Comments
IVREC	char	Drug subj received I.V.(L-Levo/C-Comp)		Collected at CRF.
POREC	char	Drug subj received P.O.(L-Levo/C-Comp)		Collected at CRF.
DOSES	num	Number of Actual Doses Taken		Collected at CRF.
SD_ROUTE	num	Study Drug Route (1-IV;2-PO;3-IV&PO)		Collected at CRF.
IV_DOSE	num	Total IV doses		Collected at CRF.
IV_DAYS	num	Total IV days		Collected at CRF.
DAYSON	num	Days on Therapy		Collected at CRF.
QUALIFY	num	Subj Meets Criteria to qual PS(1-N/2-Y)		Collected at CRF.
ASSESS	char	Does subj qualify for PS? (N/Y)		Collected at CRF.
BACTER	num	Bacteremic(1-N;2-Y)		Collected at CRF.
PATH	num	Code: 1-Admission Pathogen		Collected at CRF.
WITHDRWF	char	Decode:withdraw/early		Collected at CRF.
REASF	char	Decode:Reason for early withdrawal		Collected at CRF.
BASEHGT	char	Baseline Height in cm		Element will be grouped to protect PII
BASEWGT	char	Baseline Weight in kg		Element will be grouped to protect PII
CLINRPS	num	Clinical Response at Poststudy - num		Collected at CRF.

Variable	Type	Label	Codes	Comments
CLINRETF	char	EOT Clinical Response format		Collected at CRF.
CLINRESF	char	Posttherapy Clinical Response format		Collected at CRF.
CLINRPSF	char	Clinical Response at Poststudy format		Collected at CRF.
DRGTKN	char	Study Drug taken w/in 1st 3 days(Y/N)		Collected at CRF.
POSTADMV	char	Subj has post adm vitals info(Y/N)		Collected at CRF.
POSTADML	char	Subj has post adm stand lab info(Y/N)		Collected at CRF.
ITT	char	Intent-to-Treat Evaluable: N=No, Y=Yes		Collected at CRF.
MITT	char	Modified ITT Evaluable: N=No, Y=Yes		Collected at CRF.
SAFE	char	Safety Evaluable: N=No, Y=Yes		Collected at CRF.
MICROEV	char	Microbiologically Eval: N=No, Y=Yes		Collected at CRF.
ACTDRG	num	Actual Study drug code		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
RNOMED	char	Subj Rand but did not rec Study Drug(Y)		Collected at CRF.
ECT	char	Effective Antimicro thru Posttherapy		Collected at CRF.

Variable	Type	Label	Codes	Comments
POSTECT	char	Effective Antimicro between PT and PS		Collected at CRF.
EOTEECT	char	Effective Antimicro thru EOT		Collected at CRF.
D2ECT	char	Effective Antimicro thru Day 2		Collected at CRF.
D3ECT	char	Effective Antimicro thru Day 3		Collected at CRF.
PROTOCOL	char	Study Protocol number		Collected at CRF.
EVALDAY5	num	EOT CR Ev Day(EOTdt-Start StdyMedDt+1)		Collected at CRF.
EVALDAY6	num	PT CR Ev Day(TOCdt-Start StdyMedDt+1)		Collected at CRF.
EVALDAY7	num	PS CR Ev Day(PSdt-Start StdyMedDt+1)		Collected at CRF.
WBC	num	Central Lab Admission WBC value		Collected at CRF.
ADMDATDY	num	Relative Admission Day from Demo		If ADMDATE and REFERENCE DATE not missing then perform below logic to calculate , If ADMDATE less than REFERENCE DATE then (ADMDATE - REFERENCE DATE). Else if ADMDATE is greater than equal to REFERENCE DATE then (ADMDATE- REFERENCE DATE) +1.

Variable	Type	Label	Codes	Comments
EVAL2DY	num	Relative DAY 2 Clinical Resp Visit Day		If EVALDTD2 and REFERENCE DATE not missing then perform below logic to calculate EVALDYD2, If EVALDTD2 less than REFERENCE DATE then (EVALDTD2 - REFERENCE DATE). Else if EVALDTD2 is greater than equal to REFERENCE DATE then (EVALDTD2- REFERENCE DATE) +1.
EVAL3DY	num	Relative DAY 3 Clinical Resp Visit Day		If EVALDTD3 and REFERENCE DATE not missing then perform below logic to calculate EVALDYD3, If EVALDTD3 less than REFERENCE DATE then (EVALDTD3 - REFERENCE DATE). Else if EVALDTD3 is greater than equal to REFERENCE DATE then (EVALDTD3- REFERENCE DATE) +1.
EVALETDY	num	Relative EOT Clinical Response Visit Day		If EVALDTET and REFERENCE DATE not missing then perform below logic to calculate EVALDYET, If EVALDTET less than REFERENCE DATE then (EVALDTET - REFERENCE DATE). Else if EVALDTET is greater than equal to REFERENCE DATE then (EVALDTET- REFERENCE DATE) +1.
EVALOCDY	num	Relative PT Clinical Response Visit Day		If EVALDTC and REFERENCE DATE not missing then perform below logic to calculate EVALDYOC, If EVALDTC less than REFERENCE DATE then (EVALDTC - REFERENCE DATE). Else if EVALDTC is greater than equal to REFERENCE DATE then (EVALDTC- REFERENCE DATE) +1.

Variable	Type	Label	Codes	Comments
EVALPSDY	num	Relative Clinical Eval Day for Poststudy		If EVALDTPS and REFERENCE DATE not missing then perform below logic to calculate EVALDYPS, If EVALDTPS less than REFERENCE DATE then (EVALDTPS - REFERENCE DATE). Else if EVALDTPS is greater than equal to REFERENCE DATE then (EVALDTPS- REFERENCE DATE) +1.
VDY	num	Relative Visit 1A Day		If VDT1A and REFERENCE DATE not missing then perform below logic to calculate VDY1A, If VDT1A less than REFERENCE DATE then (VDT1A - REFERENCE DATE). Else if VDT1A is greater than equal to REFERENCE DATE then (VDT1A- REFERENCE DATE) +1.

1.4.21. KEY STUDY MEDICATION INFORMATION – KEYSMED

Dataset	KEYSMED
Creating program	keysmmed.sas
Description	KEY STUDY MEDICATION INFORMATION
Unique identifier	DSUBNUM
Sorted by	DSUBNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines : STOP,START,STRTSTDY,STOPSTDY,STOP2,START2, STRTFLAG

Variable	Type	Label	Codes	Comments
DAY3	num	Days of Meds in the first 3 DAYS		Collected at CRF.
DAYS	num	Days on Therapy (counting actual days)		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
DOSES	num	Number of Actual Doses Taken		Collected at CRF.
TAMDOSE	num	Total Doses Taken AM		Collected at CRF.
TPMDOSE	num	Total Doses Taken PM		Collected at CRF.

Variable	Type	Label	Codes	Comments
DOSES2	num	Number of 2nd Actual Doses Taken(iv/po)		Collected at CRF.
TAMDOSE2	num	Total 2nd Doses Taken AM (iv/po)		Collected at CRF.
TPMDOSE2	num	Total 2nd Doses Taken PM (iv/po)		Collected at CRF.
SD_ROUTE	num	Study Drug Route (1-IV;2-PO;3-IV&PO)		Collected at CRF.
IV_DOSE	num	Total IV doses		Collected at CRF.
IV_DAYS	num	Total IV days		Collected at CRF.
DAYSON	num	Days on Therapy (Stop-Start)+1		Collected at CRF.
LOST_AM	num	Total Lost Capsules AM		Collected at CRF.
LOST_PM	num	Total Lost Capsules PM		Collected at CRF.
LOST	num	Total Lost Capsules		Collected at CRF.

Variable	Type	Label	Codes	Comments
STOP2DY	num	Relative Stop Day of PO in IV subjects		If STOP2 and REFERENCE DATE not missing then perform below logic to calculate , If STOP2 less than REFERENCE DATE then (STOP2 - REFERENCE DATE). Else if STOP2 is greater than equal to REFERENCE DATE then (STOP2- REFERENCE DATE) +1.
START2DY	num	Relative Start Day of PO in IV subjects		If START2 and REFERENCE DATE not missing then perform below logic to calculate , If START2 less than REFERENCE DATE then (START2 - REFERENCE DATE). Else if START2 is greater than equal to REFERENCE DATE then (START2- REFERENCE DATE) +1.

1.4.22. MICRO LABS FOR PATHOGENS – KEYTYP

Dataset	KEYTYP
Creating program	keytyp.sas
Description	MICRO LABS FOR PATHOGENS
Unique identifier	DUNQSUB,SOURCEF,PATHF,TESTDRGF,SPECDDY,SPECTM,ORGNUM
Sorted by	DUNQSUB,SOURCEF,PATHF,TESTDRGF,SPECDDY,SPECTM,ORGNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due missing values: EOTOUT,SUBINI,BIRTHDT,SEX,SEXF,RACEF,LASTNAME,INVNAME,AGE,IND, SUPER,SUPERF,SUPERSE,SITEINF,SPECDDATF,SPECDESS,LAB,ACCNUM,VERBATI M,ORGCMT, ADMDATE,STOP,START,STRTSTDY,EVALDTET,EVALDTC, SPECDDT,V1CULT,SPECDDATE, AEROB,STOPSTDY, CLINRES, CLINRET, CLINRPS, ERAD2, OUTC, OUTCOME, PATH, TESTDRG, SUSCEPT, POSTOUT, SOURCE

Variable	Type	Label	Codes	Comments
FULLINF	char	FULLINF		Collected at CRF.
GRAMNP	num	Gram neg(2-gna;4-gnan)/pos(1-gpa;3-gpan)		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
ERADDDAY	num	Resolution of Eradication Day		Collected at CRF.
CENSOR	num	1-Resolv Day Rt-Censor value;0-Obs val		Collected at CRF.

Variable	Type	Label	Codes	Comments
HOUTC	num	Acute Hosp Subj Inf Outcome(1-E,3-P,6-U)		Collected at CRF.
PERIOD	num	Study period code		Collected at CRF.
HERAD	num	Acute Hosp. Subj erad(1-E,2-P,3-U)		Collected at CRF.
EOTERAD	num	Overall subject micro resp at EOT -num		Collected at CRF.
ERAD	num	Overall subj micro resp at PT - num		Collected at CRF.
POSTERAD	num	Overall subject micro resp at PS - num		Collected at CRF.
CULTNO	num	Culture number		Collected at CRF.
CULTNUM	num	Blood culture number		Collected at CRF.
RESPTFL	char	Acquisition to Resistance flag at PT		Collected at CRF.
RESETFL	char	Acquisition to Resistance flag at EOT		Collected at CRF.
EVAL	char	Highest Eval:Micro/mITT/ITT/Safe/Une v		Collected at CRF.
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

Variable	Type	Label	Codes	Comments
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
STRATUM	num	Subject stratification		Collected at CRF.
QUALIFY	num	Subj Meets Criteria to qual PS(1-N/2-Y)		Collected at CRF.
ASSESS	char	Qualifies for PS visit Y/N		Collected at CRF.
WITHDRAW	num	Withdraw/early(1=No,2=Yes,3=Unk)		Collected at CRF.
REAS	num	Reason for early withdrawal		Collected at CRF.
CLINRETF	char	EOT Clinical Response format		Collected at CRF.
CLINRESF	char	Posttherapy Clinical Response format		Collected at CRF.
CLINRPSF	char	Clinical Response at Poststudy format		Collected at CRF.
ITT	char	Intent-to-Treat Evaluable: N=No, Y=Yes		Collected at CRF.
MITT	char	Modified ITT Evaluable: N=No, Y=Yes		Collected at CRF.
SAFE	char	Safety Evaluable: N=No, Y=Yes		Collected at CRF.
MICROEV	char	Microbiologically Eval: N=No, Y=Yes		Collected at CRF.
ACTDRG	num	Actual Study Drug Taken (1-Levo/2-Comp)		Collected at CRF.

Variable	Type	Label	Codes	Comments
ACTDRGDE	char	Study drug description		Collected at CRF.
ECT	char	Effective Antimicro thru Posttherapy		Collected at CRF.
POSTECT	char	Effective Antimicro between PT and PS		Collected at CRF.
EOTECT	char	Effective Antimicro thru EOT		Collected at CRF.
D2ECT	char	Effective Antimicro thru Day 2		Collected at CRF.
D3ECT	char	Effective Antimicro thru Day 3		Collected at CRF.
PROTOCOL	char	Study Protocol number		Collected at CRF.
RPT	char	Rpt		Collected at CRF.
PATHCNT	num	Subject Count of Admission Pathogens		Collected at CRF.
TESTDRGF	char	Decode:Test Drug Name		Collected at CRF.
SOURCEF	char	formatted source of culture		Collected at CRF.
GROWTH	char	Pathogen growth		Collected at CRF.
PATHF	char	Decode:Pathogen		Collected at CRF.
INFDESC	char	Dictionary Description for pathogen		Collected at CRF.
PERIODF	char	Decode:PERIOD		Collected at CRF.
P_ECT	char	Effective concomitant therapy-pathogen		Collected at CRF.
LABF	char	Decode:lab		Collected at CRF.

Variable	Type	Label	Codes	Comments
SUSCEPTF	char	Decode:Overall Susceptibility		Collected at CRF.
SUSX	char	Susceptibility Code for MIC		Collected at CRF.
ORGNUM	char	Blood Culture number		Collected at CRF.
MICUNIT	char	MIC UNITS		Collected at CRF.
MICFLAG	char	Micro Isolate Identification- local cult		Collected at CRF.
MIC	char	MIC Result		Collected at CRF.
SPECTM	num	Time Specimen taken		Collected at CRF.
FAILOK	char	N=Ind PT Result Fail outside TOC Window		Collected at CRF.
GROWTHOK	char	>=100,000 CFUm/L for outcome deter		Collected at CRF.
OUTCOMEF	char	Decode:Micro. response at posttherapy		Collected at CRF.
OUTCF	char	Decode:PT Mic rp w/out window applied		Collected at CRF.
EOTOUTF	char	Decode:micro. response at EOT		Collected at CRF.
POSTOUTF	char	Decode:Micro. response at poststudy		Collected at CRF.
DAYS	num	Study Day		Collected at CRF.
ORGANISM	char	Organism Abbreviation		Collected at CRF.
EOTERADF	char	Decode:EOTerad		Collected at CRF.

Variable	Type	Label	Codes	Comments
ERADF	char	Decode:Erad		Collected at CRF.
ERAD2F	char	Decode:Erad2		Collected at CRF.
POSERADF	char	Decode:Posterad		Collected at CRF.
ADMDATDY	num	Relative Admission Day from Demo		If ADMDATE and REFERENCE DATE not missing then perform below logic to calculate , If ADMDATE less than REFERENCE DATE then (ADMDATE - REFERENCE DATE). Else if ADMDATE is greater than equal to REFERENCE DATE then (ADMDATE- REFERENCE DATE) +1.
EVALDYET	num	Relative EOT Clinical Response Visit Day		If EVALDTET and REFERENCE DATE not missing then perform below logic to calculate EVALDYET, If EVALDTET less than REFERENCE DATE then (EVALDTET - REFERENCE DATE). Else if EVALDTET is greater than equal to REFERENCE DATE then (EVALDTET- REFERENCE DATE) +1.
EVALDYOC	num	Relative PT Clinical Response Visit Day		If EVALDTC and REFERENCE DATE not missing then perform below logic to calculate EVALDYOC, If EVALDTC less than REFERENCE DATE then (EVALDTC - REFERENCE DATE). Else if EVALDTC is greater than equal to REFERENCE DATE then (EVALDTC- REFERENCE DATE) +1.
SPECDY	num	Relative Specimen Day		If SPECDATE and REFERENCE DATE not missing then perform below logic to calculate SPECDY, If SPECDT less than REFERENCE DATE then (SPECDT - REFERENCE DATE). Else if SPECDT is greater than equal to REFERENCE DATE then (SPECDT- REFERENCE DATE) +1.

1.4.23. LOCAL LAB COLLECTION – LCUL

Dataset	LCUL
Creating program	lcul.sas
Description	LOCAL LAB COLLECTION
Unique identifier	DUNQSUB,SPECYD,PERIOD,FULLINF,MIC
Sorted by	DUNQSUB,SPECYD,PERIOD,FULLINF,MIC
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due missing values or due to non significant elements: SUBINI,PAGE,PAGEID,SPECYD,PATH,VERBATIM,SOURCE,ACCNUM,RPT,NOTD ONE,LASTNAME,INVNAME,LAB, STOP, START, STRTSTDY, STOPSTDY, SPECYDF, STRTFLAG, SPECTDATE, SUSCEPT, TESTDRG

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study Protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
PERIOD	num	Study Period code		Collected at CRF.
PERIODF	char	Study Period description		Collected at CRF.

Variable	Type	Label	Codes	Comments
SELECTE1	num	Denotes selected analysis pathogen		Collected at CRF.
FULLINF	char	Infect dictionary code		Collected at CRF.
INFDESC	char	Decode:fullinf		Collected at CRF.
CULTNO	num	Culture number		Collected at CRF.
P_ECT	char	Effective concomitant therapy-pathogen		Collected at CRF.
PATHF	char	Decode: pathogen code		Collected at CRF.
MIC	char	MIC value		Collected at CRF.
MICUNIT	char	MIC unit		Collected at CRF.
TESTDRGF	char	Test drug - char		Collected at CRF.
SUSX	char	Susceptibility - short char		Collected at CRF.
SUSCEPTF	char	Susceptibility - character		Collected at CRF.
GROWTH	char	Pathogen growth		Collected at CRF.
SOURCEF	char	Decode:source of culture (urine)		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
LABF	char	Decode:lab		Collected at CRF.

Variable	Type	Label	Codes	Comments
SPEC DY	num	Relative Specimen culture Day		If SPEC DATE and REFERENCE DATE not missing then perform below logic to calculate , If SPEC DATE less than REFERENCE DATE then (SPEC DATE - REFERENCE DATE). Else if SPEC DATE is greater than equal to REFERENCE DATE then (SPEC DATE- REFERENCE DATE) +1.

1.4.24. PERTINENT MEDICAL HISTORY – MHAB

Dataset	MHAB
Creating program	mhab.sas
Description	PERTINENT MEDICAL HISTORY
Unique identifier	DUNQSUB,BODYSYS,VDY,PERIOD
Sorted by	DUNQSUB,BODYSYS,VDY,PERIOD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due missing values or due to non significant elements: SUBINI,PAGE,PAGEID,NOTDONE,VDATEDT,BSYSCODE,NORMABN,VERBATIM, OTHER,LASTNAME,INVNAME, STOP, START, STRTSTDY, STOPSTDY, VDATEF, STRTFLAG, VDATE

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
PERIOD	num	Study period code		Collected at CRF.
PERIODF	char	Study period description		Collected at CRF.

Variable	Type	Label	Codes	Comments
BODYSYS	char	Body system description		Collected at CRF.
NORMABNF	char	Decode:normal/abnormal		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
VDY	num	Relative Visit Day		If VDATE and REFERENCE DATE not missing then perform below logic to calculate , If VDATE less than REFERENCE DATE then (VDATE - REFERENCE DATE). Else if VDATE is greater than equal to REFERENCE DATE then (VDATE- REFERENCE DATE) +1.

1.4.25. MARKEDLY ABNORMAL LABS – MLAB

Dataset	MLAB
Creating program	mlab.sas
Description	MARKEDLY ABNORMAL LABS
Unique identifier	DUNQSUB,LABORDER,SPEC DY
Sorted by	DUNQSUB,LABORDER,SPEC DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due missing values: ACCNO,INITIAL,SEX,SUBINI,BIRTHDT,INVNAME,LASTNAME,RACE,RACEF,AGE,ABSLABV,ABSBASE,MIDPOINT, SPEC DT,START,STOP, STOPSTDY,SPEC DATE, SUBCNT

Variable	Type	Label	Codes	Comments
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
LABTST	char	Lab code		Collected at CRF.
PERIOD	num	Study Period		Collected at CRF.
PERIODF	char	Study Period description		Collected at CRF.
PROTOCOL	char	Study Protocol Number		Collected at CRF.
LABSPEC	char	Lab Test description		Collected at CRF.
LABVAL	num	Lab val - numeric result		Collected at CRF.

Variable	Type	Label	Codes	Comments
LOW	char	Low Reference Range		Collected at CRF.
HIGH	char	High Reference Range		Collected at CRF.
FLAG	char	Alert Flag		Collected at CRF.
SPECTM	char	Collection Time		Collected at CRF.
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
DAYSON	num	Days on Therapy		Collected at CRF.
GROUP	char	Lab Group		Collected at CRF.
DAY	num	Study Day		Collected at CRF.
RPT	char	Repeat Test Flag		Collected at CRF.
LABCLS	char	Lab Class		Collected at CRF.
LABDESC	char	Lab Test description		Collected at CRF.
ACTDRG	num	Actual Study Drug Taken (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Treatment Group - character		Collected at CRF.
NLOW	num	Low		Collected at CRF.
NHIGH	num	High		Collected at CRF.
BFLAG	num	Baseline Flag		Collected at CRF.
PTHFLAG	num	1=use as Posttherapy Lab		Collected at CRF.
UNIT	char	Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
BASE	num	Baseline Lab value		Collected at CRF.
TREATEMR	char	Treatment-Emergent Flag (Y/N)		Collected at CRF.
CHANGE	num	Change in Lab Value from Admission		Collected at CRF.
LABORDER	num	Lab order		Collected at CRF.
DIFF	num	Difference from Baseline		Collected at CRF.
PERDIFF	num	Percentage Difference		Collected at CRF.
FLAGKEEP	num	Markedly Flag		Collected at CRF.
MFLAG	char	Markedly result		Collected at CRF.
SPEC DY	num	Relative Sample Collection Day		If SPEC DATE and REFERENCE DATE not missing then perform below logic to calculate , If SPEC DATE less than REFERENCE DATE then (SPEC DATE - REFERENCE DATE). Else if SPEC DATE is greater than equal to REFERENCE DATE then (SPEC DATE- REFERENCE DATE) +1.

1.4.26. MARKEDLY ABNORMAL LAB BASE – MLABBASE

Dataset	MLABBASE
Creating program	mlabbase.sas
Description	MARKEDLY ABNORMAL LAB BASE
Unique identifier	DUNQSUB,LABORDER,SPEC DY
Sorted by	DUNQSUB,LABORDER,SPEC DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due missing values: ACCNO,INITIAL,SUBINI,BIRTHDT,INVNAME,LASTNAME,RACE,RACEF,AGE, BFLAG,ABSLABV,BASE,ABSBASE,CHANGE,MIDPOINT,DIFF,PERDIFF,SPEC DT, SPEC DATE,START, STOP,STOPSTDY, SEX, SUBCNT

Variable	Type	Label	Codes	Comments
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
LABTST	char	Lab code		Collected at CRF.
PERIOD	num	Study Period		Collected at CRF.
PERIODF	char	Study Period description		Collected at CRF.
PROTOCOL	char	Study Protocol Number		Collected at CRF.
LABSPEC	char	Lab Test description		Collected at CRF.
LABVAL	num	Lab val - numeric result		Collected at CRF.

Variable	Type	Label	Codes	Comments
LOW	char	Low Reference Range		Collected at CRF.
HIGH	char	High Reference Range		Collected at CRF.
FLAG	char	Alert Flag		Collected at CRF.
SPECTM	char	Collection Time		Collected at CRF.
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
DAYSON	num	Days on Therapy		Collected at CRF.
GROUP	char	Lab Group		Collected at CRF.
DAY	num	Study Day		Collected at CRF.
RPT	char	Repeat Test Flag		Collected at CRF.
LABCLS	char	Lab Class		Collected at CRF.
LABDESC	char	Lab Test description		Collected at CRF.
ACTDRG	num	Actual Study Drug Taken (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Treatment Group - character		Collected at CRF.
NLOW	num	Low		Collected at CRF.
NHIGH	num	High		Collected at CRF.
PTHFLAG	num	1=use as Posttherapy Lab		Collected at CRF.
UNIT	char	Units		Collected at CRF.

Variable	Type	Label	Codes	Comments
TREATEMR	char	Treatment-Emergent Flag (Y/N)		Collected at CRF.
LABORDER	num	Lab order		Collected at CRF.
FLAGKEEP	num	Markedly Flag		Collected at CRF.
MFLAG	char	Markedly result		Collected at CRF.
SPEC DY	num	Relative Sample Collection Day		If SPEC DATE and REFERENCE DATE not missing then perform below logic to calculate , If SPEC DATE less than REFERENCE DATE then (SPEC DATE - REFERENCE DATE). Else if SPEC DATE is greater than equal to REFERENCE DATE then (SPEC DATE- REFERENCE DATE) +1.

1.4.27. CENTRAL LAB OTHER LABS – OLAB

Dataset	OLAB
Creating program	olab.sas
Description	CENTRAL LAB OTHER LABS
Unique identifier	DUNQSUB,LABTST,SPEC DY
Sorted by	DUNQSUB,LABTST,SPEC DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due missing values: ACCNO,INITIAL,SEX,LABVERB,FLAG,SUBINI,BIRTHDT,INVNAME,LASTNAME,RACE,RACEF,AGE, SPEC DT,START,STOP, STOPSTDY,SPEC DATE, VISITDT, LABORDER

Variable	Type	Label	Codes	Comments
PERIOD	num	Study period code		Collected at CRF.
PERIODF	char	Decode:Study Period		Collected at CRF.
PROTOCOL	char	Study Protocol Number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
LABSPEC	char	Lab Test description		Collected at CRF.
LABVAL	num	Lab Val - for calculation		Collected at CRF.
SPECTM	char	Specimen Collection Time		Collected at CRF.

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
DAYSON	num	Days on Therapy		Collected at CRF.
GROUP	char	Lab Group		Collected at CRF.
DAY	num	Study Day		Collected at CRF.
RPT	char	Repeat Test Flag		Collected at CRF.
LABTST	char	Lab Code		Collected at CRF.
LABCLS	char	Lab Class		Collected at CRF.
LABDESC	char	Lab Test description		Collected at CRF.
ACTDRG	num	Actual Study Drug Taken (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Treatment Group - character		Collected at CRF.
ADMFLAG	num	1=use as Admission Lab		Collected at CRF.
PTHFLAG	num	1=use as Posttherapy Lab		Collected at CRF.
UNIT	char	Units		Collected at CRF.
BASE	num	Baseline(Admission) Lab Value		Collected at CRF.
TREATEMR	char	Treatment-Emergent Flag (Y/N)		Collected at CRF.
CHANGE	num	Change in Lab Value from Admission		Collected at CRF.

Variable	Type	Label	Codes	Comments
SPEC DY	num	Relative Sample Collection Day		If SPEC DATE and REFERENCE DATE not missing then perform below logic to calculate , If SPEC DATE less than REFERENCE DATE then (SPEC DATE - REFERENCE DATE). Else if SPEC DATE is greater than equal to REFERENCE DATE then (SPEC DATE- REFERENCE DATE) +1.
VISIT DY	num	Relative Visit Day		If VISIT DT and REFERENCE DATE not missing then perform below logic to calculate , If VISIT DT less than REFERENCE DATE then (VISIT DT - REFERENCE DATE). Else if VISIT DT is greater than equal to REFERENCE DATE then (VISIT DT - REFERENCE DATE) +1.

1.4.28. HEALTH OUTCOME QUESTIONNAIRE – OUTCOME

Dataset	OUTCOME
Creating program	outcome.sas
Description	HEALTH OUTCOME QUESTIONNAIRE
Unique identifier	DUNQSUB
Sorted by	DUNQSUB
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements: SUBINI,PAGE,PAGEID,VDATEDT,OUT1,OUT1DUE1,OUT1DUE2,OUT2,OUT2DUE1,OUT3,OUT3DUE2,OUT4,LASTNAME,INVNAME ,STOP, START, STRTSTDY, STOPSTDY, VDATEF, STRTFLAG, VDATE, OUT2DUE2, OUT3DUE1

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
PERIOD	num	Study period code		Collected at CRF.
PERIODF	char	Study period description		Collected at CRF.

Variable	Type	Label	Codes	Comments
NOTDONE	num	Page not done (-6=Not done)		Collected at CRF.
OUT1DAYS	char	Number of days hospitalized		Collected at CRF.
ND	num	Section not done (1)		Collected at CRF.
OUT1F	char	Decode:out1		Collected at CRF.
OUT1D1F	char	Decode:out1due1		Collected at CRF.
OUT2D2F	char	Decode:out2due2		Collected at CRF.
OUT2VIS	char	Number of er visits		Collected at CRF.
OUT2F	char	Decode:out2		Collected at CRF.
OUT2D1F	char	Decode:out2due1		Collected at CRF.
OUT3VIS	char	Number of doctor office visits		Collected at CRF.
OUT3F	char	Decode:out3		Collected at CRF.
OUT3D1F	char	Decode:out3due31		Collected at CRF.
OUT3D2F	char	Decode:out3due2		Collected at CRF.
OUT4F	char	Decode:out4		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
OUT1D2F	char	Decode:out1due2		Collected at CRF.

Variable	Type	Label	Codes	Comments
VDY	num	Relative Visit Day		If VDATE and REFERENCE DATE not missing then perform below logic to calculate , If VDATE less than REFERENCE DATE then (VDATE - REFERENCE DATE). Else if VDATE is greater than equal to REFERENCE DATE then (VDATE- REFERENCE DATE) +1.

1.4.29. PERTINENT PHYSICAL EXAM – PHYS

Dataset	PHYS
Creating program	phys.sas
Description	PERTINENT PHYSICAL EXAM
Unique identifier	DUNQSUB,VDY,PSYSTEM,ACTDRGDE,PABNOF
Sorted by	DUNQSUB,VDY,PSYSTEM,ACTDRGDE,PABNOF
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements: SUBINI,PAGE,PAGEID,VDATEDT,PABNO,VERBATIM,LASTNAME,INVNAME STOP, START, STRTSTDY, STOPSTDY, VDATEF, STRTFLAG,VDATE, OTHER

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study Protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
RPT	char	Repeated/Unscheduled Visit (R)		Collected at CRF.
PERIOD	num	Study Period code		Collected at CRF.

Variable	Type	Label	Codes	Comments
PERIODF	char	Study Period description		Collected at CRF.
NOTDONE	num	Page not done (-6=Not done)		Collected at CRF.
ND	num	Section not done(1=ND)		Collected at CRF.
PSYSCODE	num	Body system code		Collected at CRF.
PSYSTEM	char	Body system description		Collected at CRF.
PABNOF	char	Decode:normal/abnormal		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
VDY	num	Relative Visit Day		If VDATE and REFERENCE DATE not missing then perform below logic to calculate , If VDATE less than REFERENCE DATE then (VDATE - REFERENCE DATE). Else if VDATE is greater than equal to REFERENCE DATE then (VDATE- REFERENCE DATE) +1.

1.4.30. ORAL (PO) STUDY MEDICATION LABELS – POLABEL

Dataset	POLABEL
Creating program	polabel.sas
Description	ATTACHED STUDY MEDICATION_P.O. LABELS
Unique identifier	DUNQSUB
Sorted by	DUNQSUB
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due missing values or due to non significant elements: SUBINI,PAGE,PAGEID,NOTDONE,POLABEL,LASTNAME,INVNAME, STOP, START, STRTSTDY, STOPSTDY, STRTFLAG

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
PERIOD	num	Study period code		Collected at CRF.
PERIODF	char	Study period description		Collected at CRF.

Variable	Type	Label	Codes	Comments
POLABELF	char	Decode:polabel		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity

1.4.31. POST ELIGIBILITY – POSTELIG

Dataset	POSTELIG
Creating program	postelig.sas
Description	POST STUDY ELIGIBILITY
Unique identifier	DUNQSUB
Sorted by	DUNQSUB
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due missing values or due to non significant elements: SUBINI,PAGE,PAGEID,NOTDONE,QUALIFY,LASTNAME,INVNAME, STOP, START, STRTSTDY, STOPSTDY, STRTFLAG

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
PERIOD	num	Study period code		Collected at CRF.
PERIODF	char	Study period description		Collected at CRF.
QUALIFYF	char	Decode:qualify		Collected at CRF.

Variable	Type	Label	Codes	Comments
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity

1.4.32. URINE PREGNANCY TEST – PREG

Dataset	PREG
Creating program	preg.sas
Description	URINE PREGNANCY TEST
Unique identifier	DUNQSUB,PERIOD
Sorted by	DUNQSUB,PERIOD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements: SUBINI,PAGE,PAGEID,VDATEDT,PREGPERF,PREGRES,LASTNAME,INVNAME, , STOP, START, STRTSTDY, STOPSTDY, VDATEF, STRTFLAG, VDATE

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity

Variable	Type	Label	Codes	Comments
PROTOCOL	char	Study Protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
RPT	char	Repeated/Unscheduled Visit (R)		Collected at CRF.
PERIOD	num	Study Period code		Collected at CRF.
PERIODF	char	Study Period description		Collected at CRF.
NOTDONE	num	Page not done (-6=Not done)		Collected at CRF.
PREGPRFF	char	Decode:pregperf		Collected at CRF.
PREGRESF	char	Decode:pregres		Collected at CRF.
ND	num	Section not done(1=ND)		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
VDY	num	Relative Visit Day		If VDATE and REFERENCE DATE not missing then perform below logic to calculate , If VDATE less than REFERENCE DATE then (VDATE - REFERENCE DATE). Else if VDATE is greater than equal to REFERENCE DATE then (VDATE- REFERENCE DATE) +1.

1.4.33. RANDOMIZATION FILE – RANDOM

Dataset	RANDOM
Creating program	random.sas
Description	RANDOMIZATION FILE
Unique identifier	DSUBNUM
Sorted by	DSUBNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines : INVNAME,BLCKCODE,RANCODE,MEDCODE,LASTNAME, RNOMED2, NOTRAND

Variable	Type	Label	Codes	Comments
DRUGCODE	num	DrugCode		Collected at CRF.
DRUGNAME	char	Name of randomized study drug		Collected at CRF.
ASSIGNED	num	Assigned		Collected at CRF.
TRTNAME	char	Name of actual study drug taken		Collected at CRF.
ACTDRG	num	Actual Study drug code		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
XACTDRG	num	Randomized Study drug code		Collected at CRF.

Variable	Type	Label	Codes	Comments
COMBODIF	num	Subj received iv/po trt levo/comp (1)		Collected at CRF.
IVREC	char	Drug subj received I.V.(L-Levo/C-Comp)		Collected at CRF.
POREC	char	Drug subj received P.O.(L-Levo/C-Comp)		Collected at CRF.
ADRG	num	Drug subj rec from medcode(1-L/2-C)		Collected at CRF.
TNAME	char	Decode:Adrg(1-Levo/2-Comp)		Collected at CRF.
STRATID	char	Stratization ID		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity

1.4.34. RISK ASSESSMENT – RISK

Dataset	RISK
Creating program	risk.sas
Description	RISK ASSESSMENT
Unique identifier	DUNQSUB
Sorted by	DUNQSUB
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due missing values or due to non significant elements: SUBINI,PAGE,PAGEID,NOTDONE,VDATEDT,RSK1,RSK2,RSK3,RSK4,RSK4SPEC,L ASTNAME,INVNAME, STOP, START, STRTSTDY, STOPSTDY, VDATEF, STRFLAG, VDATE

Variable	Type	Label	Codes	Comments
PROTOCOL	char	Study protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
PERIOD	num	Study period code		Collected at CRF.
PERIODF	char	Study period description		Collected at CRF.
RSK1F	char	Decode:rsk1		Collected at CRF.

Variable	Type	Label	Codes	Comments
RSK2F	char	Decode:rsk2		Collected at CRF.
RSK3F	char	Decode:rsk3		Collected at CRF.
RSK4F	char	Decode:rsk4		Collected at CRF.
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
VDY	num	Relative Visit Day		If VDATE and REFERENCE DATE not missing then perform below logic to calculate , If VDATE less than REFERENCE DATE then (VDATE - REFERENCE DATE). Else if VDATE is greater than equal to REFERENCE DATE then (VDATE- REFERENCE DATE) +1.

1.4.35. RANDOMIZATION INFORMATION – RNDM

Dataset	RNDM
Creating program	rndm.sas
Description	RANDOMIZATION INFORMATION
Unique identifier	DUNQSUB
Sorted by	DUNQSUB
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due missing values or due to non significant elements: SUBINI,PAGE,PAGEID,NOTDONE,VDATEDT,RNDM1,RNDM2,RNDM3,RNDMNUM,KITNUM,LASTNAME,INVNAME, STOP, START, STRTSTDY, STOPSTDY, VDATEF, STRTFLAG, STRATUM, VDATE

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
PERIOD	num	Study period code		Collected at CRF.
PERIODF	char	Study period description		Collected at CRF.

Variable	Type	Label	Codes	Comments
RNDM1F	char	Decode:acute pyelo (1=comm,2=inst)		Collected at CRF.
RNDM2F	char	Decode:cuti w/out chr indw cath(1=c,2=i)		Collected at CRF.
RNDM3F	char	Decode:cuti w/chr indw cath(1=c,2=i)		Collected at CRF.
STRATUMF	char	Decode:subject stratification		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2- Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
VDY	num	Relative Visit Day		If VDATE and REFERENCE DATE not missing then perform below logic to calculate , If VDATE less than REFERENCE DATE then (VDATE - REFERENCE DATE). Else if VDATE is greater than equal to REFERENCE DATE then (VDATE- REFERENCE DATE) +1.

1.4.36. SUBJECT ROSTER – ROSTER

Dataset	ROSTER
Creating program	roster.sas
Description	SUBJECT ROSTER
Unique identifier	DSUBNUM
Sorted by	DSUBNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines: COMMENT,INITIAL,MEDCODE,LASTNAME, ENROLLDT

Variable	Type	Label	Codes	Comments
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
ACTDRG	num	Treatment Group(1=Levo,2=Comp)		Collected at CRF.
XACTDRG	num	Randomized Treatment Group		Collected at CRF.
STRATID	char	Stratization ID		Collected at CRF.
ENROLLED	char	Subject Enrolled (Y/N)		Collected at CRF.

1.4.37. URINARY SIGNS – SIGN

Dataset	SIGN
Creating program	sign.sas
Description	URINARY SIGNS
Unique identifier	DUNQSUB,PERIOD
Sorted by	DUNQSUB,PERIOD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements: SUBINI,PAGE,PAGEID,VDATEDT,SIGN,TUNIT,VERBATIM,LASTNAME,INVNAME,STOP, START, STRTSTDY, STOPSTDY, VDATEF, STRTFLAG,VDATE

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study Protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
PERIOD	num	Study period code		Collected at CRF.
PERIODF	char	Study Period description		Collected at CRF.

Variable	Type	Label	Codes	Comments
NOTDONE	num	Page not done (-6=Not done)		Collected at CRF.
SIGDESC	char	Sign		Collected at CRF.
SIGNNUM	num	Sign number		Collected at CRF.
SIGNF	char	Decode:sign present		Collected at CRF.
TEMP	char	History temperature		Collected at CRF.
TEMP_C	num	Temperature in celsius		Collected at CRF.
TEMP_F	num	Temperature in fahrenheit		Collected at CRF.
TUNITF	char	Decode:history temperature UNIT		Collected at CRF.
ND	num	Sign section not done(1)		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
RPT	char	Rpt		Collected at CRF.
VDY	num	Relative Visit Day		If VDATE and REFERENCE DATE not missing then perform below logic to calculate , If VDATE less than REFERENCE DATE then (VDATE - REFERENCE DATE). Else if VDATE is greater than equal to REFERENCE DATE then (VDATE- REFERENCE DATE) +1.

1.4.38. CENTRAL LAB STANDARD LABS – SLAB

Dataset	SLAB
Creating program	slab.sas
Description	CENTRAL LAB STANDARD LABS
Unique identifier	DUNQSUB,PERIOD,LABTST,SPEC DY
Sorted by	DUNQSUB,PERIOD,LABTST,SPEC DY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information : ACCNO,INITIAL,SUBINI,BIRTHDT,INVNAME,LASTNAME,RACE,RACEF,AGE,SPEC DT,SPEC DATE,START,STOP, STOPSTDY, SEX

Variable	Type	Label	Codes	Comments
PERIOD	num	Study Period		Collected at CRF.
PERIODF	char	Decode:Study Period		Collected at CRF.
PROTOCOL	char	Study Protocol Number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
LABSPEC	char	Lab Test description		Collected at CRF.
LABVAL	num	Lab Val - for calculation		Collected at CRF.
LABVERB	char	Lab - Text Result		Collected at CRF.
LOW	char	Low Reference Range		Collected at CRF.

Variable	Type	Label	Codes	Comments
HIGH	char	High Reference Range		Collected at CRF.
FLAG	char	Alert Flag		Collected at CRF.
SPECTM	char	Specimen Collection Time		Collected at CRF.
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
DAYSON	num	Days on Therapy		Collected at CRF.
GROUP	char	Lab Group		Collected at CRF.
DAY	num	Study Day		Collected at CRF.
RPT	char	Repeat Test FLAG		Collected at CRF.
LABTST	char	Lab Code		Collected at CRF.
LABCLS	char	Lab Class		Collected at CRF.
LABDESC	char	Lab Test description		Collected at CRF.
ACTDRG	num	Actual Study Drug Taken (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Treatment Group - character		Collected at CRF.
NLOW	num	Low		Collected at CRF.
NHIGH	num	High		Collected at CRF.
ADMFLAG	num	1=use as Admission Lab		Collected at CRF.
PTHFLAG	num	1=use as Posttherapy Lab		Collected at CRF.

Variable	Type	Label	Codes	Comments
ABSLABV	num	Absolu Val: Neutro/Esoinophil/Lymphocyte		Collected at CRF.
UNIT	char	UNITS		Collected at CRF.
BASE	num	Baseline(Admission) Lab Value		Collected at CRF.
ABSBASE	num	Baseline(adm) Lab Value in Absolute		Collected at CRF.
TREATEMR	char	Treatment-Emergent Flag (Y/N)		Collected at CRF.
CHANGE	num	Change in Lab Value from Admission		Collected at CRF.
LABORDER	num	Lab Order		Collected at CRF.
SPEC DY	num	Relative Sample Collection Day		If SPEC DT and REFERENCE DATE not missing then perform below logic to calculate SPEC DY, If SPEC DT less than REFERENCE DATE then (SPEC DT - REFERENCE DATE). Else if SPEC DT is greater than equal to REFERENCE DATE then (SPEC DT - REFERENCE DATE) +1.

1.4.39. STUDY MEDICATION – SMED

Dataset	SMED
Creating program	smed.sas
Description	STUDY MEDICATION
Unique identifier	DUNQSUB,SMEDDY
Sorted by	DUNQSUB,SMEDDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due missing values or due to non significant elements: SUBINI,PAGE,PAGEID,NOTDONE,SMEDDT,LASTNAME,INVNAME, STOP, START, STRTSTDY, STOPSTDY, SMEDDATF, STRTFLAG,SMEDDATE

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
PERIOD	num	Study period code		Collected at CRF.
PERIODF	char	Study period description		Collected at CRF.
SMEDDAY	num	Study day medication taken		Collected at CRF.

Variable	Type	Label	Codes	Comments
TDOSEAM	char	Time of 1st am dose taken		Collected at CRF.
TDOSEAMF	num	Time of 1st am dose taken flag		Collected at CRF.
ADMINAM	num	Am dose (1=iv,2-po,3=not taken)		Collected at CRF.
ADMINPM	num	Pm dose (1=iv,2-po,3=not taken)		Collected at CRF.
TDOSEPM	char	Time of 1st pm dose taken		Collected at CRF.
TDOSEPMF	num	Time of 1st pm dose taken flag		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
SMEDDY	num	Relative Study med Day		If SMEDDATE and REFERENCE DATE not missing then perform below logic to calculate , If SMEDDATE less than REFERENCE DATE then (SMEDDATE - REFERENCE DATE). Else if SMEDDATE is greater than equal to REFERENCE DATE then (SMEDDATE- REFERENCE DATE) +1.

1.4.40. SUPERINFECTION – SUBA

Dataset	SUBA
Creating program	suba.sas
Description	SUPERINFECTION
Unique identifier	DUNQSUB,PERIOD
Sorted by	DUNQSUB,PERIOD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due missing values or due to non significant elements: SUBINI,PAGE,PAGEID,NOTDONE,CULTAKE,YESSPEC,SPEC DT,SOURCE,SPEC PAT H,VERBATIM,AUGMIC,CEFTMIC,BACTMIC,AMPMIC,LEVOMIC,CIPRMIC,CIPRS US,OXACMIC,AZITMIC,TETRMIC,CULTNO,PATHF,PATH,LASTNAME,INVNAME, STOP, START, STRTSTDY, STOPSTDY,SPEC DATE, SPEC DATF, STRTFLAG

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study Protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
PERIOD	num	Study Period code		Collected at CRF.

Variable	Type	Label	Codes	Comments
PERIODF	char	Study Period description		Collected at CRF.
CULTAKEF	char	Decode:new infection		Collected at CRF.
SITEINF	char	Site of new infection		Collected at CRF.
SOURCEF	char	Decode:source of culture (urine)		Collected at CRF.
SPECPTHF	char	Decode:description code for specimen		Collected at CRF.
GROWTH	char	Pathogen growth		Collected at CRF.
AUGSUS	char	Susceptibility to augmentin		Collected at CRF.
CEFTSUS	char	Susceptibility to ceftriaxone		Collected at CRF.
BACTSUS	char	Susceptibility to bactrim		Collected at CRF.
AMPSUS	char	Susceptibility to ampicillin		Collected at CRF.
LEVOSUS	char	Susceptibility to levofloxacin		Collected at CRF.
OXACSUS	char	Susceptibility to oxacillin		Collected at CRF.
AZITSUS	char	Susceptibility to azithromycin		Collected at CRF.
TETRSUS	char	Susceptibility to tetracycline		Collected at CRF.
FULLINF	char	Dictionary code for pathogen		Collected at CRF.
RPT	char	Rpt		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.

Variable	Type	Label	Codes	Comments
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
INFDESC	char	Dictionary description for pathogen		Collected at CRF.
SPEC DY	num	Relative Specimen Day		If SPEC DATE and REFERENCE DATE not missing then perform below logic to calculate , If SPEC DATE less than REFERENCE DATE then (SPEC DATE - REFERENCE DATE). Else if SPEC DATE is greater than equal to REFERENCE DATE then (SPEC DATE- REFERENCE DATE) +1.

1.4.41. SUBSTANCE ABUSE HISTORY – SUBABUSE

Dataset	SUBABUSE
Creating program	subabuse.sas
Description	SUBSTANCE ABUSE HISTORY
Unique identifier	DUNQSUB
Sorted by	DUNQSUB
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due missing values or due to non significant elements: SUBINI,PAGE,PAGEID,NOTDONE,VDATEDT,ABUSE,ABUSEHIS,LASTNAME,INVN AME, STOP, START, STRTSTDY, STOPSTDY, VDATEF, STRTFLAG,VDATE

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
PERIOD	num	Study period code		Collected at CRF.
PERIODF	char	Study period description		Collected at CRF.

Variable	Type	Label	Codes	Comments
ABUSEF	char	Decode:substance abuse		Collected at CRF.
ABUSHF	char	Decode:substance abuse history		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
VDAY	num	Relative Visit Day		If VDATE and REFERENCE DATE not missing then perform below logic to calculate , If VDATE less than REFERENCE DATE then (VDATE - REFERENCE DATE). Else if VDATE is greater than equal to REFERENCE DATE then (VDATE- REFERENCE DATE) +1.

1.4.42. SUBJECT LOG – SUBLOG

Dataset	SUBLOG
Creating program	sublog.sas
Description	SUBJECT LOG
Unique identifier	DSUBNUM
Sorted by	DSUBNUM
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information : MREVALCM,LETFAIL, QADT, NOTRAND, CLEANDT, CRFRECV, DSFTLKDT

Variable	Type	Label	Codes	Comments
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
MREVALCD	char	Md. monitor micro evaluability		Collected at CRF.
WAIVER	char	Md. monitor waiver		Collected at CRF.
MREVAL	char	Micro evaluable (Yes/No)		Collected at CRF.
MMSTRAT	num	Med. mon. subject stratification		Collected at CRF.

Variable	Type	Label	Codes	Comments
MM2STRAT	num	2nd med. mon. subject stratification		Collected at CRF.
INDETER	num	Med Mon Input Indeterminate Clin Resp		Collected at CRF.
LETFAILF	char	Decode:Letfail(1=Y)		Collected at CRF.
REENROLL	num	Subject reenrolled in study(1)		Collected at CRF.
COMBODIF	num	Subj received iv/po trt levo/comp (1)		Collected at CRF.
IVREC	char	Drug subj received I.V.(L-Levo/C-Comp)		Collected at CRF.
POREC	char	Drug subj received P.O.(L-Levo/C-Comp)		Collected at CRF.
CLEANDY	num	Relative Day of clean		If CLEANDT and REFERENCE DATE not missing then perform below logic to calculate CLEANDY, If CLEANDT less than REFERENCE DATE then (CLEANDT - REFERENCE DATE). Else if CLEANDT is greater than equal to REFERENCE DATE then (CLEANDT- REFERENCE DATE) +1.

Variable	Type	Label	Codes	Comments
DSFTLKDY	num	Relative Day of soft lock		If DSFTLKDT and REFERENCE DATE not missing then perform below logic to calculate DSFTLKDY, If DSFTLKDT less than REFERENCE DATE then (DSFTLKDT - REFERENCE DATE). Else if DSFTLKDT is greater than equal to REFERENCE DATE then (DSFTLKDT- REFERENCE DATE) +1.
CRFRECDY	num	Relative Day crf received inhouse		If CRFRECV and REFERENCE DATE not missing then perform below logic to calculate , If CRFRECV less than REFERENCE DATE then (CRFRECV - REFERENCE DATE). Else if CRFRECV is greater than equal to REFERENCE DATE then (CRFRECV- REFERENCE DATE) +1.
QADY	num	Relative Day of Data sent for qa review		If QADT and REFERENCE DATE not missing then perform below logic to calculate , If QADT less than REFERENCE DATE then (QADT - REFERENCE DATE). Else if QADT is greater than equal to REFERENCE DATE then (QADT - REFERENCE DATE) +1.

1.4.43. COLONIZATION_PARTICIPATION SUB_STUDY – SUBSTUDY

Dataset	SUBSTUDY
Creating program	substudy.sas
Description	COLONIZATION_PARTICIPATION SUB_STUDY
Unique identifier	DUNQSUB
Sorted by	DUNQSUB
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due missing values or due to non significant elements: SUBINI,PAGE,PAGEID,NOTPAR,VDATEDT,CONSENT,SWAB1,SWAB2,AE,CONMED,LASTNAME,INVNAME,ND, STOP, START, STRTSTDY, STOPSTDY, VDATEF, STRTFLAG,VDATE

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
PERIOD	num	Study period code		Collected at CRF.
PERIODF	char	Study period description		Collected at CRF.

Variable	Type	Label	Codes	Comments
NOTDONE	num	Page not done (-6=Not done)		Collected at CRF.
NOTPARF	char	Decode:notpar		Collected at CRF.
NA	num	NA		Collected at CRF.
CONSENTF	char	Decode:consent		Collected at CRF.
SWAB1F	char	Decode:swab1		Collected at CRF.
SWAB2F	char	Decode:swab2		Collected at CRF.
AEF	char	Decode:ae		Collected at CRF.
CONMEDF	char	Decode:conmed		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
VDY	num	Relative Visit Day		If VDATE and REFERENCE DATE not missing then perform below logic to calculate , If VDATE less than REFERENCE DATE then (VDATE - REFERENCE DATE). Else if VDATE is greater than equal to REFERENCE DATE then (VDATE- REFERENCE DATE) +1.

1.4.44. URINARY SYMPTOMS – SYMP

Dataset	SYMP
Creating program	symp.sas
Description	URINARY SYMPTOMS
Unique identifier	DUNQSUB,VDY,SYMPNUM,PERIOD
Sorted by	DUNQSUB,VDY,SYMPNUM,PERIOD
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements: SUBINI,PAGE,PAGEID,VDATEDT,SYMPTOM,VERBATIM,LASTNAME,INVNAME,STOP,START,STRSTDY,STOPSTDY,VDATEF,STRFLAG,VDATE,SPECIFY

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study Protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
RPT	char	Repeated/Unscheduled visit(R)		Collected at CRF.
PERIOD	num	Study period code		Collected at CRF.

Variable	Type	Label	Codes	Comments
PERIODF	char	Study Period description		Collected at CRF.
NOTDONE	num	Page not done (-6=Not done)		Collected at CRF.
SYMPDESC	char	Symptom		Collected at CRF.
SYMPNUM	num	Symptom number		Collected at CRF.
SYMPTOMF	char	Decode:symptom present		Collected at CRF.
ND	num	ND		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
VDY	num	Relative Visit Day		If VDATE and REFERENCE DATE not missing then perform below logic to calculate , If VDATE less than REFERENCE DATE then (VDATE - REFERENCE DATE). Else if VDATE is greater than equal to REFERENCE DATE then (VDATE- REFERENCE DATE) +1.

1.4.45. CENTRAL LAB URINE CULTURES– UCUL

Dataset	UCUL
Creating program	ucul.sas
Description	CENTRAL LAB URINE CULTURES
Unique identifier	DUNQSUB,VDY,PATHF
Sorted by	DUNQSUB,VDY,PATHF
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements: SUBINI,PAGE,PAGEID,VDATEDT,SOURCE,SPEC DT,VERBATIM,LASTNAME,INVN AME,LAB, STOP, START, STRTSTDY, STOPSTDY,SPEC DATE, VDATEF, SPEC DATF, STR TFLAG, VDATE, PATH

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study Protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
PERIOD	num	Study period code		Collected at CRF.
PERIODF	char	Study Period description		Collected at CRF.

Variable	Type	Label	Codes	Comments
SOURCEF	char	Decode:source of culture (urine)		Collected at CRF.
CULTNO	num	Culture number		Collected at CRF.
PATHF	char	Decode: pathogen code		Collected at CRF.
P_ECT	char	Effective concomitant therapy-pathogen		Collected at CRF.
FULLINF	char	Infect dictionary code		Collected at CRF.
SELECTE1	num	Denotes selected analysis pathogen		Collected at CRF.
DRUG	char	Decode:drug code		Collected at CRF.
DRUGCODE	char	ECT drug code - who drug dictionary		Collected at CRF.
INFDESC	char	Decode:fullinf		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
LABF	char	Decode:lab		Collected at CRF.

Variable	Type	Label	Codes	Comments
VDY	num	Relative Visit Day		If VDATE and REFERENCE DATE not missing then perform below logic to calculate , If VDATE less than REFERENCE DATE then (VDATE - REFERENCE DATE). Else if VDATE is greater than equal to REFERENCE DATE then (VDATE- REFERENCE DATE) +1.
SPEC DY	num	Relative Specimen culture Day		If SPECDATE and REFERENCE DATE not missing then perform below logic to calculate , If SPECDATE less than REFERENCE DATE then (SPECDATE - REFERENCE DATE). Else if SPECDATE is greater than equal to REFERENCE DATE then (SPECDATE- REFERENCE DATE) +1.

1.4.46. UNBLINDING – UNBLIND

Dataset	UNBLIND
Creating program	unblind.sas
Description	UNBLINDING
Unique identifier	DUNQSUB
Sorted by	DUNQSUB
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due missing values or due to non significant elements: SUBINI,PAGE,PAGEID,NOTDONE,VDATEDT,REVEALED,RVLDT,REASON,LASTNAME,INVNAME, STOP, START, STRTSTDY, STOPSTDY, RVLDATEF, RVLDATE , STRTFLAG,VDATEF,VDATE

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Study protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
PERIOD	num	Study period code		Collected at CRF.
PERIODF	char	Study period description		Collected at CRF.

Variable	Type	Label	Codes	Comments
REVEALDF	char	Decode:revealed		Collected at CRF.
RVLTIME	char	Revealed time		Collected at CRF.
RVLTIMEF	num	Revealed time flag		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity
VDY	num	Relative Visit Day		If VDATE and REFERENCE DATE not missing then perform below logic to calculate , If VDATE less than REFERENCE DATE then (VDATE - REFERENCE DATE). Else if VDATE is greater than equal to REFERENCE DATE then (VDATE- REFERENCE DATE) +1.

1.4.47. VITAL SIGNS – VITALS

Dataset	VITALS
Creating program	vitals.sas
Description	VITAL SIGNS
Unique identifier	DUNQSUB,VDY
Sorted by	DUNQSUB,VDY
Notes	Below listed variables will be dropped from dataset to protect PII as per HIPAA and EMA guidelines or due to repetition of the information or due to non significant elements: SUBINI,PAGE,PAGEID,VDATEDT,HGTUNIT,WGTUNIT,TEMPUNIT,TEMPTYPE,LA STNAME,INVNAME, HGT_I, HGT, WGT_L, WGT, STOP, START, STRTSTDY, STOPSTDY, WGTUNITF, HGTUNITF, VDATEF, STRTFLAG, OTHSPEC,VDATE

Variable	Type	Label	Codes	Comments
DUNQSUB	char	Unique Subject ID Assign for De-identity		Randomly assigned Unique Subject ID for De-identity
PROTOCOL	char	Protocol number		Collected at CRF.
DSUBNUM	num	Subject number Assigned for De-identity		Randomly assigned Subject number for De-identity.
DPATIENT	char	Patient Id Assigned for De-identity		Randomly assigned Patient Id for De-identity
RPT	char	Repeated/Unscheduled Visit (R)		Collected at CRF.

Variable	Type	Label	Codes	Comments
PERIOD	num	Study Period code		Collected at CRF.
PERIODF	char	Study Period description		Collected at CRF.
NOTDONE	num	Page not done (-6=Not done)		Collected at CRF.
HGT_C	num	Height in centimeters		Group element to protect PII.
WGT_K	num	Weight in kilograms		Group element to protect PII.
TEMPER	num	Temperature		Collected at CRF.
TEMPUNTF	char	Decode:tempunit		Collected at CRF.
TEMP_C	num	Temperature in celsius		Collected at CRF.
TEMP_F	num	Temperature in fahrenheit		Collected at CRF.
TEMPTYPF	char	Decode:temperature type		Collected at CRF.
PULSE	num	Heart rate		Collected at CRF.
BPSYS	num	Systolic blood pressure		Collected at CRF.
BPDIAS	num	Diastolic blood pressure		Collected at CRF.
RESP	num	Respiratory rate		Collected at CRF.
ND	num	ND		Collected at CRF.
ACTDRG	num	Study drug code (1-Levo/2-Comp)		Collected at CRF.
ACTDRGDE	char	Study drug description		Collected at CRF.
DINVNUM	num	Unique Inv num Assigned for De-identity		Randomly assigned Unique Investigator number for De-identity

Variable	Type	Label	Codes	Comments
VDY	num	Relative Visit Day		If VDATE and REFERENCE DATE not missing then perform below logic to calculate , If VDATE less than REFERENCE DATE then (VDATE - REFERENCE DATE). Else if VDATE is greater than equal to REFERENCE DATE then (VDATE- REFERENCE DATE) +1.