



IBM Clinical Development Unique Pages

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| Study Name: | PBPK_6278 |
| Page Option | All |

AE_SAE

Page

(Visit ID = 265173, Page ID =)

Unique Identifier page-265173-265173-265173-

| | | | |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| | | <input type="checkbox"/> | AE_SAE.NO AE |
| Adverse Events | | | |
| | AE Number | <input type="text"/> | AE_SAE.AE SPID |
| SDV | * AE Term | <input type="text"/> | AE_SAE.AE TERM |
| SDV | * AE onset date | <input type="text"/> | AE_SAE.AE STDT |
| SDV | * AE onset time | <input type="text"/> : <input type="text"/> | AE_SAE.AE (HH24:MI) STTM |
| SDV | * AE severity | <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe | AE_SAE.AE SEV |
| SDV | * Relationship of AE with study drug | <input type="radio"/> Not related <input type="radio"/> Unlikely related <input type="radio"/> Possibly related <input type="radio"/> Related | AE_SAE.AE REL |
| SDV | * Rationale for relationship with study drug (only provide if relationship is possibly, probably or definitely related) | <input type="text"/> | AE_SAE.AE RELST |
| SDV | * AE Outcome | <input type="radio"/> Recovered / Resolved <input type="radio"/> Recovering / Resolving <input type="radio"/> Not recovered / Not resolved <input type="radio"/> Recovered / Resolved with sequelae <input type="radio"/> Fatal <input type="radio"/> Unknown | AE_SAE.AE OUT |
| SDV | * AE stop date | <input type="text"/> | AE_SAE.AE ENDT |
| SDV | * AE stop time | <input type="text"/> : <input type="text"/> | AE_SAE.AE (HH24:MI) ENDTM |
| SDV | * Ongoing | <input type="radio"/> Ongoing | AE_SAE.AE ONGO |

| | | | |
|------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| SDV | * Action taken regarding study drug | <input type="radio"/> Dose not changed <input type="radio"/> Dose reduced <input type="radio"/> Dose increased <input type="radio"/> Drug Interrupted <input type="radio"/> Drug discontinued <input type="radio"/> Unknown <input type="radio"/> Not applicable | AE_SAE.AE ACN |
| SDV | * If study drug was interrupted, is this adverse event the primary reason for study drug interruption? | <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not Applicable | AE_SAE.AE DINRD |
| SDV | * If study drug was discontinued, is this adverse event the primary reason for study drug discontinuation? | <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not Applicable | AE_SAE.AE DIS |
| SDV | * If study drug was discontinued, interrupted, or reduced (dechallenged), did AE diminish/abate? | <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not Applicable | AE_SAE.AE DIMTD |
| SDV | * If study drug was restarted (Rechallenge) did AE recur? | <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not Applicable | AE_SAE.AE RAPR |
| Possible alternate causes of the AE (check all that apply) | | | |
| SDV | Primary disease under study | <input type="checkbox"/> | AE_SAE.PRI MDIS |
| SDV | Study procedure | <input type="checkbox"/> | AE_SAE.ST UDPROC |
| SDV | * Specify | <input type="text"/> | AE_SAE.ST PRSPEC |
| SDV | Concomitant illness | <input type="checkbox"/> | AE_SAE.CO NCOMIL |
| SDV | * Specify | <input type="text"/> | AE_SAE.ILL SPEC |
| SDV | Concomitant medication | <input type="checkbox"/> | AE_SAE.CO NCOMED |
| SDV | * Specify | <input type="text"/> | AE_SAE.CO NSPEC |
| SDV | Other known or suspected cause | <input type="checkbox"/> | AE_SAE.OT HCAUS |
| SDV | * Specify | <input type="text"/> | AE_SAE.OT HSPEC |
| SDV | None (Only applicable if study drug related and considered only cause of AE) | <input type="checkbox"/> | AE_SAE.AL TNONE |
| SDV | * Was this event serious? (If yes, check all that apply) | <input type="radio"/> Yes <input type="radio"/> No | AE_SAE.AE SER |

| | | | |
|------------|-------------------------------------------------------------------------------|--------------------------|---------------------|
| SDV | Death | <input type="checkbox"/> | AE_SAE.AE SDTH |
| SDV | Life-threatening | <input type="checkbox"/> | AE_SAE.AE SLIFE |
| SDV | Require inpatient hospitalization or prolongation of existing hospitalization | <input type="checkbox"/> | AE_SAE.AE SHOSP |
| SDV | Persistent or significant disability/incapacity | <input type="checkbox"/> | AE_SAE.AE SDISAB |
| SDV | Congenital anomaly or birth defect | <input type="checkbox"/> | AE_SAE.AE SCONG |
| SDV | Important medical event | <input type="checkbox"/> | AE_SAE.AE SMIE |

Please complete the SAE Narrative page in the Visit Pages box at the top of the page.

Relevant Laboratory and Diagnostic Details

| | | | |
|------------|------------------------------------------------------------------------|-------------------------------------------------------|---------------------|
| SDV | * Were there any relevant laboratory or diagnostic tests for this SAE? | <input type="radio"/> Yes <input type="radio"/> No | AE_SAE.SA ELABYN |
|------------|------------------------------------------------------------------------|-------------------------------------------------------|---------------------|

Please complete the Relevant Laboratory or Diagnostic Details page in the Visit Pages box at the top of the page.

Concomitant Medications

| | | | |
|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|--------------------|
| SDV | * Was the subject on any concomitant medications during the onset of this SAE? If yes, complete a concomitant medication page for each medication(s). | <input type="radio"/> Yes <input type="radio"/> No | AE_SAE.SA ECMID |
|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|--------------------|

Please complete the Concomitant Medications page in the Visit Pages box at the top of the page.

Investigator Verification

| | | | |
|--|----------------------------------------------------------------------------------------------------------------------------------------|--------------------------|---------------------|
| | I verify that this SAE report form accurately displays the results of the examination, tests, evaluations and treatments noted within. | <input type="checkbox"/> | AE_SAE.PIS IG |
| | MedDRA Preferred Term | <input type="text"/> | AE_SAE.MM MEDDRA |


CLAB

Page

(Visit ID = 265231, Page ID =)

Unique Identifier page-265231-265231-265231-

Date and Time

* Lab date  CLAB.LABD
T

* Lab time : CLAB.LABT (HH24:MI)
M

* Lab Name  CLAB.LABN
AME

Labs

| | | | | | | | | | |
|----------------------|--------------------------------------|--------------------------|----------------------|----------------------|-----------------------------------|---------------------------------------------|-------------|-----------------------------|----------------------|
| Alkaline Phosphatase | Yes <input checked="" type="radio"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | (H H 2 4: M I) | (x x x x x x x x x) | Q/L Q/L | Please complete an AE form. | <input type="text"/> |
| | No <input type="radio"/> | | | | | | | | |
| | CLAB .ALP ND | CLAB .ALP SM | CLAB .ALP DT | CLAB .ALP TM | CLAB .ALP VA | CLAB .ALP UN | | | CLAB .ALP RSLT |
| Albumin | Yes <input checked="" type="radio"/> | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | (H H 2 4: M I) | (x x x x x x x x x) | g/dL g/L | Please complete an AE form. | <input type="text"/> |
| | No <input type="radio"/> | | | | | | | | |
| | CLAB .ALB ND | CLAB .ALB SM | CLAB .ALB DT | CLAB .ALB TM | CLAB .ALB VA | CLAB .ALB UN | | | CLAB .ALR SLT |

If additional lab tests were run if performed per standard of care, please record in Chemistry Labs or Hematology Labs page at Logs/Rpts visit



CM

Page

(Visit ID = 265177, Page ID =)

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| | | |
|-------------------------------|--------------------------------|-----------------------------------|
| Concomitant Medication Number | <input type="text"/> | CM.CMSPID |
| * Medication Name | <input type="text"/> | CM.CMTRT |
| * Indication | <input type="text"/> | CM.CMINDC |
| Total daily dose | <input type="text"/> | CM.CMTDD (format xxxxx.xx) OSE |
| * Dose Unit | <input type="text" value="U"/> | CM.CMDOS U |
| * Start Date | <input type="text" value=""/> | CM.CMSTD T |
| Stop Date | <input type="text" value=""/> | CM.CMEND T |
| Ongoing | <input type="radio"/> Ongoing | CM.CMONG |

DM

Page

(Visit ID = 265206, Page ID =)

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DEMOGRAPHICS

| | | | |
|------------|---------------------------------------------------------------------------|-------------------------------------------------------|-------------------------------|
| SDV | * Date of Birth | <input type="text"/> | DM.BRTHD T |
| | * Is patient more than 12 months old at the time Informed Consent signed? | <input type="radio"/> Yes <input type="radio"/> No | DM.YRSMT HS |
| | * Gestational age at birth in weeks | <input type="text"/> | DM.GEAGE (format xx) |
| | * Body weight at birth in kg | <input type="text"/> | DM.BRTHW T (format xxx.xx) |

SEX

| | | | |
|------------|--------------------------------------------|------------------------------------------------------------|---------------|
| | * Sex | <input type="radio"/> Male <input type="radio"/> Female | DM.SEX |
| SDV | Is the patient of child-bearing potential? | <input type="radio"/> Yes <input type="radio"/> No | DM.CHDPO T |

RACE (check all that apply)

| | | | |
|--|-------------------------------------------|--------------------------|-----------------|
| | White | <input type="checkbox"/> | DM.WHITE |
| | Black or African American | <input type="checkbox"/> | DM.BLACK |
| | American Indian or Alaska Native | <input type="checkbox"/> | DM.NATIVE |
| | Asian | <input type="checkbox"/> | DM.ASIAN |
| | Native Hawaiian or Other Pacific Islander | <input type="checkbox"/> | DM.HAWAII |
| | Other | <input type="checkbox"/> | DM.RCOTHE ER |
| | * Other Race, specify | <input type="text"/> | DM.RACEO TH |

ETHNICITY

| | | | |
|--|-------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| | * Ethnicity | <input type="radio"/> Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown | DM.ETHNIC |
|--|-------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|



DOSEPK

Page

(Visit ID = 265242, Page ID =)

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| | | | |
|------------|---------------------------------|----------------------------------------------------------------------------------------------------|------------------------------|
| SDV | * Dose weight (kg) | <input type="text"/> | DOSE.DOS EWT (format xxx.xx) |
| SDV | * Which drug is patient taking? | <input type="radio"/> Clindamycin <input type="radio"/> TMP-SMX (trimethoprim-sulfamethoxazole) | DOSE.RXTK N |

Reminder: Dose amounts should only be for the TMP (trimethoprim) component.

| Dose 1 | | | |
|------------|----------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| SDV | Please check if Dose 1 not administered | <input type="checkbox"/> | DOSE.DAY ND1 |
| SDV | * Reason not administered: | <input type="radio"/> Patient completed the study <input type="radio"/> Patient discharged <input type="radio"/> Other | DOSE.RSN AD1 |
| SDV | * Other, specify: | <input type="text"/> | DOSE.ROT HSY1 |
| SDV | * Route Administered | <input type="radio"/> IV <input type="radio"/> PO | DOSE.ROU TE1 |
| SDV | * Type | <input type="radio"/> Capsules or tablets <input type="radio"/> Suspension | DOSE.TYPE 1 |
| SDV | * Dose Administered (mg) | <input type="text"/> | DOSE.ADMI N1 (format xxx) |
| SDV | * Start Date | <input type="text"/> | DOSE.ASST DT1 |
| SDV | * Start Time | <input type="text"/> : <input type="text"/> | DOSE.ASST TM1 (HH24:MI) |
| SDV | * Dose Date | <input type="text"/> | DOSE.PO1D T |
| SDV | * Dose Time | <input type="text"/> : <input type="text"/> | DOSE.PO1T M (HH24:MI) |
| | Please check if time given is estimated time. | <input type="checkbox"/> | DOSE.STTM 1EST |
| SDV | * Infusion rate (mg/hour) | <input type="text"/> | DOSE.INFR T1 (format xxxx) |
| SDV | * Did patient vomit/spit up within one hour of dosing? | <input type="radio"/> Yes <input type="radio"/> No | DOSE.ORE NTDS1 |
| SDV | * What percentage of dose is estimated to have been vomited/spit up? | <input type="text"/> | DOSE.PERV OM1 (format xxx) |

| | | | |
|------------|-----------------------------------------------|-------------------------------------------------------|---------------------------------|
| SDV | * Was patient re-dosed? | <input type="radio"/> Yes <input type="radio"/> No | DOSE.RED S1YN |
| SDV | * Dose Administered (mg) | <input type="text"/> | DOSE.RED (format xxx) OSE1 |
| SDV | * Re-dose Date | <input type="text"/> | DOSE.RED S1DT |
| SDV | * Re-dose Time | <input type="text"/> : <input type="text"/> | DOSE.RED (HH24:MI) S1TM |
| | Please check if time given is estimated time. | <input type="checkbox"/> | DOSE.RED S1EST |
| SDV | * Dosing Interrupted? | <input type="radio"/> Yes <input type="radio"/> No | DOSE.INTR PT1 |
| SDV | * Interrupted Stop Date: | <input type="text"/> | DOSE.INTD T1 |
| SDV | * Interrupted Stop Time: | <input type="text"/> : <input type="text"/> | DOSE.INTT (HH24:MI) M1 |
| SDV | * Dosing Restarted? | <input type="radio"/> Yes <input type="radio"/> No | DOSE.REST RT1 |
| SDV | * Restarted Date: | <input type="text"/> | DOSE.RSTR DT1 |
| SDV | * Restarted Time: | <input type="text"/> : <input type="text"/> | DOSE.RSTR (HH24:MI) TM1 |
| SDV | * Infusion rate (mg/hour) | <input type="text"/> | DOSE.INFR (format xxxx) TRE1 |
| SDV | * Final Stop Date | <input type="text"/> | DOSE.FNSP DT1 |
| SDV | * Final Stop Time | <input type="text"/> : <input type="text"/> | DOSE.FNSP (HH24:MI) TM1 |

| PK Timepoint | PK Timepoint | Please check if sample not taken | Sample Date | Sample Time | Please check to confirm sample taken after flush time | Sample Accession Number |
|----------------------------------------|-----------------------------------------|------------------------------------------------------------------------------------------------------------------------------|----------------------|-------------------------------|-------------------------------------------------------|-------------------------|
| 0 to 10 mins after dose end | 1 to 3 hours after dose end | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> (H24:MI) | <input type="checkbox"/> | <input type="text"/> |
| | | DOSE.PKSMP1ND | DOSE.PKSMP1DT | DOSE.PKSMP1TM | DOSE.PKFLSH1 | DOSE.PKSMP1NM |
| 2 to 4 hours after dose start | 6 to 8 hours after dose start | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> (H24:MI) | <input type="checkbox"/> | <input type="text"/> |
| | | DOSE.PKSMP2ND | DOSE.PKSMP2DT | DOSE.PKSMP2TM | DOSE.PKFLSH2 | DOSE.PKSMP2NM |
| < 30 mins prior to next scheduled dose | < 30 mins prior to next scheduled dose | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> (H24:MI) | <input type="checkbox"/> | <input type="text"/> |
| | | DOSE.PKSMP3ND | DOSE.PKSMP3DT | DOSE.PKSMP3TM | DOSE.PKFLSH3 | DOSE.PKSMP3NM |
| Dose 2 | | | | | | |
| SDV | Please check if Dose 2 not administered | <input type="checkbox"/> | | DOSE.DAYND2 | | |
| SDV | * Reason not administered: | <input type="radio"/> Patient completed the study <input type="radio"/> Patient discharged <input type="radio"/> Other | | DOSE.RSNAD2 | | |
| SDV | * Other, specify: | <input type="text"/> | | DOSE.ROTHSY2 | | |
| SDV | * Route Administered | <input type="radio"/> IV <input type="radio"/> PO | | DOSE.ROUTE2 | | |
| SDV | * Type | <input type="radio"/> Capsules or tablets <input type="radio"/> Suspension | | DOSE.TYPE2 | | |
| SDV | * Dose Administered (mg) | <input type="text"/> | | DOSE.ADMIN2 (format xxx) | | |
| SDV | * Start Date | <input type="text"/> | | DOSE.ASSTD2 | | |

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| SDV | * Start Time | <input type="text"/> : <input type="text"/> | DOSE.ASST (HH24:MI) TM2 |
| SDV | * Dose Date | <input type="text"/> | DOSE.PO2D T |
| SDV | * Dose Time | <input type="text"/> : <input type="text"/> | DOSE.PO2T (HH24:MI) M |
| | Please check if time given is estimated time. | <input type="checkbox"/> | DOSE.STTM 2EST |
| SDV | * Infusion rate (mg/hour) | <input type="text"/> | DOSE.INFR (format xxxx) T2 |
| SDV | * Did patient vomit/spit up within one hour of dosing? | <input type="radio"/> Yes <input type="radio"/> No | DOSE.ORE NTDS2 |
| SDV | * What percentage of dose is estimated to have been vomited/spit up? | <input type="text"/> | DOSE.PERV (format xxx) OM2 |
| SDV | * Was patient re-dosed? | <input type="radio"/> Yes <input type="radio"/> No | DOSE.RED S2YN |
| SDV | * Dose Administered (mg) | <input type="text"/> | DOSE.RED (format xxx) OSE2 |
| SDV | * Re-dose Date | <input type="text"/> | DOSE.RED S2DT |
| SDV | * Re-dose Time | <input type="text"/> : <input type="text"/> | DOSE.RED (HH24:MI) S2TM |
| | Please check if time given is estimated time. | <input type="checkbox"/> | DOSE.RED S2EST |
| SDV | * Dosing Interrupted? | <input type="radio"/> Yes <input type="radio"/> No | DOSE.INTR PT2 |
| SDV | * Interrupted Stop Date: | <input type="text"/> | DOSE.INTD T2 |
| SDV | * Interrupted Stop Time: | <input type="text"/> : <input type="text"/> | DOSE.INTT (HH24:MI) M2 |
| SDV | * Dosing Restarted? | <input type="radio"/> Yes <input type="radio"/> No | DOSE.REST RT2 |
| SDV | * Restarted Date: | <input type="text"/> | DOSE.RSTR DT2 |
| SDV | * Restarted Time: | <input type="text"/> : <input type="text"/> | DOSE.RSTR (HH24:MI) TM2 |
| SDV | * Infusion rate (mg/hour) | <input type="text"/> | DOSE.INFR (format xxxx) TRE2 |
| SDV | * Final Stop Date | <input type="text"/> | DOSE.FNSP DT2 |
| SDV | * Final Stop Time | <input type="text"/> : <input type="text"/> | DOSE.FNSP (HH24:MI) TM2 |
| Dose 3 | | | |
| SDV | Please check if Dose 3 not administered | <input type="checkbox"/> | DOSE.DAY ND3 |

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| SDV | * Reason not administered: | <input type="radio"/> Patient completed the study <input type="radio"/> Patient discharged <input type="radio"/> Other | DOSE.RSN AD3 |
| SDV | * Other, specify: | <input type="text"/> | DOSE.ROT HSY3 |
| SDV | * Route Administered | <input type="radio"/> IV <input type="radio"/> PO | DOSE.ROU TE3 |
| SDV | * Type | <input type="radio"/> Capsules or tablets <input type="radio"/> Suspension | DOSE.TYPE 3 |
| SDV | * Dose Administered (mg) | <input type="text"/> | DOSE.ADMI (format xxx) N3 |
| SDV | * Start Date | <input type="text"/> | DOSE.ASST DT3 |
| SDV | * Start Time | <input type="text"/> : <input type="text"/> | DOSE.ASST (HH24:MI) TM3 |
| SDV | * Dose Date | <input type="text"/> | DOSE.PO3D T |
| SDV | * Dose Time | <input type="text"/> : <input type="text"/> | DOSE.PO3T (HH24:MI) M |
| | Please check if time given is estimated time. | <input type="checkbox"/> | DOSE.STTM 3EST |
| SDV | * Infusion rate (mg/hour) | <input type="text"/> | DOSE.INFR (format xxxx) T3 |
| SDV | * Did patient vomit/spit up within one hour of dosing? | <input type="radio"/> Yes <input type="radio"/> No | DOSE.ORE NTDS3 |
| SDV | * What percentage of dose is estimated to have been vomited/spit up? | <input type="text"/> | DOSE.PERV (format xxx) OM3 |
| SDV | * Was patient re-dosed? | <input type="radio"/> Yes <input type="radio"/> No | DOSE.RED S3YN |
| SDV | * Dose Administered (mg) | <input type="text"/> | DOSE.RED (format xxx) OSE3 |
| SDV | * Re-dose Date | <input type="text"/> | DOSE.RED S3DT |
| SDV | * Re-dose Time | <input type="text"/> : <input type="text"/> | DOSE.RED (HH24:MI) S3TM |
| | Please check if time given is estimated time. | <input type="checkbox"/> | DOSE.RED S3EST |
| SDV | * Dosing Interrupted? | <input type="radio"/> Yes <input type="radio"/> No | DOSE.INTR PT3 |
| SDV | * Interrupted Stop Date: | <input type="text"/> | DOSE.INTD T3 |
| SDV | * Interrupted Stop Time: | <input type="text"/> : <input type="text"/> | DOSE.INTT (HH24:MI) M3 |
| SDV | * Dosing Restarted? | <input type="radio"/> Yes <input type="radio"/> No | DOSE.REST RT3 |

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| SDV | * Restarted Date: | <input type="text"/> | DOSE.RSTR DT3 |
| SDV | * Restarted Time: | <input type="text"/> : <input type="text"/> | DOSE.RSTR (HH24:MI) TM3 |
| SDV | * Infusion rate (mg/hour) | <input type="text"/> | DOSE.INFR (format xxxx) TRE3 |
| SDV | * Final Stop Date | <input type="text"/> | DOSE.FNSP DT3 |
| SDV | * Final Stop Time: | <input type="text"/> : <input type="text"/> | DOSE.FNSP (HH24:MI) TM3 |
| Dose 4 | | | |
| SDV | Please check if Dose 4 not administered | <input type="checkbox"/> | DOSE.DAY ND4 |
| SDV | * Reason not administered: | <input type="radio"/> Patient completed the study <input type="radio"/> Patient discharged <input type="radio"/> Other | DOSE.RSN AD4 |
| SDV | * Other, specify: | <input type="text"/> | DOSE.ROT HSY4 |
| SDV | * Route Administered | <input type="radio"/> IV <input type="radio"/> PO | DOSE.ROU TE4 |
| SDV | * Type | <input type="radio"/> Capsules or tablets <input type="radio"/> Suspension | DOSE.TYPE 4 |
| SDV | * Dose Administered (mg) | <input type="text"/> | DOSE.ADMI (format xxx) N4 |
| SDV | * Start Date | <input type="text"/> | DOSE.ASST DT4 |
| SDV | * Start Time | <input type="text"/> : <input type="text"/> | DOSE.ASST (HH24:MI) TM4 |
| SDV | * Dose Date | <input type="text"/> | DOSE.PO4D T |
| SDV | * Dose Time | <input type="text"/> : <input type="text"/> | DOSE.PO4T (HH24:MI) M |
| | Please check if time given is estimated time. | <input type="checkbox"/> | DOSE.STTM 4EST |
| SDV | * Infusion rate (mg/hour) | <input type="text"/> | DOSE.INFR (format xxxx) T4 |
| SDV | * Did patient vomit/spit up within one hour of dosing? | <input type="radio"/> Yes <input type="radio"/> No | DOSE.ORE NTDS4 |
| SDV | * What percentage of dose is estimated to have been vomited/spit up? | <input type="text"/> | DOSE.PERV (format xxx) OM4 |
| SDV | * Was patient re-dosed? | <input type="radio"/> Yes <input type="radio"/> No | DOSE.RED S4YN |
| SDV | * Dose Administered (mg) | <input type="text"/> | DOSE.RED (format xxx) OSE4 |
| SDV | * Re-dose Date | <input type="text"/> | DOSE.RED S4DT |

| | | | |
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| SDV | * Re-dose Time | <input type="text"/> : <input type="text"/> | DOSE.RED S4TM (HH24:MI) |
| | Please check if time given is estimated time. | <input type="checkbox"/> | DOSE.RED S4EST |
| SDV | * Dosing Interrupted? | <input type="radio"/> Yes <input type="radio"/> No | DOSE.INTR PT4 |
| SDV | * Interrupted Stop Date: | <input type="text"/> | DOSE.INTD T4 |
| SDV | * Interrupted Stop Time: | <input type="text"/> : <input type="text"/> | DOSE.INTT M4 (HH24:MI) |
| SDV | * Dosing Restarted? | <input type="radio"/> Yes <input type="radio"/> No | DOSE.REST RT4 |
| SDV | * Restarted Date: | <input type="text"/> | DOSE.RSTR DT4 |
| SDV | * Restarted Time: | <input type="text"/> : <input type="text"/> | DOSE.RSTR TM4 (HH24:MI) |
| SDV | * Infusion rate (mg/hour) | <input type="text"/> | DOSE.INFR TRE4 (format xxxx) |
| SDV | * Final Stop Date | <input type="text"/> | DOSE.FNSP DT4 |
| SDV | * Final Stop Time: | <input type="text"/> : <input type="text"/> | DOSE.FNSP TM4 (HH24:MI) |
| Dose 5 | | | |
| SDV | Please check if Dose 5 not administered | <input type="checkbox"/> | DOSE.DAY ND5 |
| SDV | * Reason not administered: | <input type="radio"/> Patient completed the study <input type="radio"/> Patient discharged <input type="radio"/> Other | DOSE.RSN AD5 |
| SDV | * Other, specify: | <input type="text"/> | DOSE.ROT HSY5 |
| SDV | * Route Administered | <input type="radio"/> IV <input type="radio"/> PO | DOSE.ROU TE5 |
| SDV | * Type | <input type="radio"/> Capsules or tablets <input type="radio"/> Suspension | DOSE.TYPE 5 |
| SDV | * Dose Administered (mg) | <input type="text"/> | DOSE.ADMI N5 (format xxx) |
| SDV | * Start Date | <input type="text"/> | DOSE.ASST DT5 |
| SDV | * Start Time | <input type="text"/> : <input type="text"/> | DOSE.ASST TM5 (HH24:MI) |
| SDV | * Dose Date | <input type="text"/> | DOSE.PO5D T |
| SDV | * Dose Time | <input type="text"/> : <input type="text"/> | DOSE.PO5T M (HH24:MI) |
| | Please check if time given is estimated time. | <input type="checkbox"/> | DOSE.STTM 5EST |
| SDV | * Infusion rate (mg/hour) | <input type="text"/> | DOSE.INFR T5 (format xxxx) |

| | | | | | | |
|-----------------------------------------------------|----------------------------------------------------------------------|-------------------------------------------------------|-----------------------|------------------------------------------------|-------------------------------------------------------|---------------------------------|
| SDV | * Did patient vomit/spit up within one hour of dosing? | <input type="radio"/> Yes <input type="radio"/> No | | | | DOSE.ORE NTDS5 |
| SDV | * What percentage of dose is estimated to have been vomited/spit up? | <input type="text"/> | | | | DOSE.PERV (format xxx) OM5 |
| SDV | * Was patient re-dosed? | <input type="radio"/> Yes <input type="radio"/> No | | | | DOSE.RED S5YN |
| SDV | * Dose Administered (mg) | <input type="text"/> | | | | DOSE.RED (format xxx) OSE5 |
| SDV | * Re-dose Date | <input type="text"/> | | | | DOSE.RED S5DT |
| SDV | * Re-dose Time | <input type="text"/> | | | | DOSE.RED (HH24:MI) S5TM |
| | Please check if time given is estimated time. | <input type="checkbox"/> | | | | DOSE.RED S5EST |
| SDV | * Dosing Interrupted? | <input type="radio"/> Yes <input type="radio"/> No | | | | DOSE.INTR PT5 |
| SDV | * Interrupted Stop Date: | <input type="text"/> | | | | DOSE.INTD T5 |
| SDV | * Interrupted Stop Time: | <input type="text"/> | | | | DOSE.INTT (HH24:MI) M5 |
| SDV | * Dosing Restarted? | <input type="radio"/> Yes <input type="radio"/> No | | | | DOSE.REST RT5 |
| SDV | * Restarted Date: | <input type="text"/> | | | | DOSE.RSTR DT5 |
| SDV | * Restarted Time: | <input type="text"/> | | | | DOSE.RSTR (HH24:MI) TM5 |
| SDV | * Infusion rate (mg/hour) | <input type="text"/> | | | | DOSE.INFR (format xxxx) TRE5 |
| SDV | * Final Stop Date | <input type="text"/> | | | | DOSE.FNSP DT5 |
| SDV | * Final Stop Time: | <input type="text"/> | | | | DOSE.FNSP (HH24:MI) TM5 |
| PK Timepoint | PK Timepoint | Please check if sample not taken | Sample Date | Sample Time | Please check to confirm sample taken after flush time | Sample Accession Number |
| Pre-dose 6 (or last dose) | Pre-dose 6 (or last dose) | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> (H H2 4: MI) | <input type="checkbox"/> | <input type="text"/> |
| | | DOSE. PKSMP 4ND | DOSE. PKSMP 4DT | DOSE. PKSMP 4TM | DOSE. PKFLS H4 | DOSE. PKSMP 4NM |
| Dose 6 (or last dose if discharged prior to dose 6) | | | | | | |

| | | | |
|------------|----------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| SDV | Please check if Dose 6 not administered | <input type="checkbox"/> | DOSE.DAY ND6 |
| SDV | * Reason not administered: | <input type="radio"/> Patient completed the study <input type="radio"/> Patient discharged <input type="radio"/> Other | DOSE.RSN AD6 |
| SDV | * Other, specify: | <input type="text"/> | DOSE.ROT HSY6 |
| SDV | * Route Administered | <input type="radio"/> IV <input type="radio"/> PO | DOSE.ROU TE6 |
| SDV | * Type | <input type="radio"/> Capsules or tablets <input type="radio"/> Suspension | DOSE.TYPE 6 |
| SDV | * Dose Administered (mg) | <input type="text"/> | DOSE.ADMI (format xxx) N6 |
| SDV | * Start Date | <input type="text"/> | DOSE.ASST DT6 |
| SDV | * Start Time | <input type="text"/> : <input type="text"/> | DOSE.ASST (HH24:MI) TM6 |
| SDV | * Dose Date | <input type="text"/> | DOSE.PO6D T |
| SDV | * Dose Time | <input type="text"/> : <input type="text"/> | DOSE.PO6T (HH24:MI) M |
| | Please check if time given is estimated time. | <input type="checkbox"/> | DOSE.STTM 6EST |
| SDV | * Infusion rate (mg/hour) | <input type="text"/> | DOSE.INFR (format xxxx) T6 |
| SDV | * Did patient vomit/spit up within one hour of dosing? | <input type="radio"/> Yes <input type="radio"/> No | DOSE.ORE NTDS6 |
| SDV | * What percentage of dose is estimated to have been vomited/spit up? | <input type="text"/> | DOSE.PERV (format xxx) OM6 |
| SDV | * Was patient re-dosed? | <input type="radio"/> Yes <input type="radio"/> No | DOSE.RED S6YN |
| SDV | * Dose Administered (mg) | <input type="text"/> | DOSE.RED (format xxx) OSE6 |
| SDV | * Re-dose Date | <input type="text"/> | DOSE.RED S6DT |
| SDV | * Re-dose Time | <input type="text"/> : <input type="text"/> | DOSE.RED (HH24:MI) S6TM |
| | Please check if time given is estimated time. | <input type="checkbox"/> | DOSE.RED S6EST |
| SDV | * Dosing Interrupted | <input type="radio"/> Yes <input type="radio"/> No | DOSE.INTR PT6 |
| SDV | * Interrupted Stop Date | <input type="text"/> | DOSE.INTD T6 |
| SDV | * Interrupted Stop Time | <input type="text"/> : <input type="text"/> | DOSE.INTT (HH24:MI) M6 |

| | | | |
|------------|---------------------------|-------------------------------------------------------|---------------------------------|
| SDV | * Dosing Restarted? | <input type="radio"/> Yes <input type="radio"/> No | DOSE.REST RT6 |
| SDV | * Restarted Date | <input type="text"/> | DOSE.RSTR DT6 |
| SDV | * Restarted Time | <input type="text"/> : <input type="text"/> | DOSE.RSTR (HH24:MI) TM6 |
| SDV | * Infusion rate (mg/hour) | <input type="text"/> | DOSE.INFR (format xxxx) TRE6 |
| SDV | * Final Stop Date | <input type="text"/> | DOSE.FNSP DT6 |
| SDV | * Final Stop Time | <input type="text"/> : <input type="text"/> | DOSE.FNSP (HH24:MI) TM6 |

| PK timepoint | PK timepoint | PK timepoint | Please check if sample not taken | Sample Date | Sample Time | Please chec k to confirm sam ple taken after flush ti me | Sample Acc ession Num ber |
|----------------------------------------------------|----------------------------------------------------|----------------------------------------------------|--------------------------------------------------------------|---------------------------|------------------------------------------------|-----------------------------------------------------------------------------|---------------------------------|
| 0 to 10 mins after dose end | 30 to 60 min s after dose end | 1 to 3 hours after dose end | <input type="checkbox"/> <input checked="" type="checkbox"/> | <input type="text"/> | <input type="text"/> (H H2 4: MI) | <input type="checkbox"/> <input checked="" type="checkbox"/> | <input type="text"/> |
| | | | DOS E.PK SMP5 ND | DOS E.PK SMP5 DT | DOS E.PK SMP5 TM | DOS E.PK FLSH 5 | DOS E.PK SMP5 NM |
| 2 to 4 hours after dose start | 2 to 4 hours after dose start | 6 to 8 hours after dose start | <input type="checkbox"/> <input checked="" type="checkbox"/> | <input type="text"/> | <input type="text"/> (H H2 4: MI) | <input type="checkbox"/> <input checked="" type="checkbox"/> | <input type="text"/> |
| | | | DOS E.PK SMP6 ND | DOS E.PK SMP6 DT | DOS E.PK SMP6 TM | DOS E.PK FLSH 6 | DOS E.PK SMP6 NM |
| < 30 mins p rior to next s cheduled do se | < 30 mins p rior to next s cheduled do se | < 30 mins p rior to next s cheduled do se | <input type="checkbox"/> <input checked="" type="checkbox"/> | <input type="text"/> | <input type="text"/> (H H2 4: MI) | <input type="checkbox"/> <input checked="" type="checkbox"/> | <input type="text"/> |
| | | | DOS E.PK SMP7 ND | DOS E.PK SMP7 DT | DOS E.PK SMP7 TM | DOS E.PK FLSH 7 | DOS E.PK SMP7 NM |

DOSEPKAD

Page

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| Additional Dose | | | |
|-----------------|----------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| SDV | Please check if Additional Dose not administered | <input type="checkbox"/> | DOSE.DAY NDAD |
| SDV | * Reason not administered: | <input type="radio"/> Patient completed the study <input type="radio"/> Patient discharged <input type="radio"/> Other | DOSE.RSN ADAD |
| SDV | * Other, specify: | <input type="text"/> | DOSE.ROT HSYAD |
| SDV | * Route Administered | <input type="radio"/> IV <input type="radio"/> PO | DOSE.ROU TEAD |
| SDV | * Type | <input type="radio"/> Capsules or tablets <input type="radio"/> Suspension | DOSE.TYPE AD |
| SDV | * Dose Administered (mg) | <input type="text"/> | DOSE.ADMI (format xxx) NAD |
| SDV | * Start Date | <input type="text"/> | DOSE.ASST DTAD |
| SDV | * Start Time | <input type="text"/> : <input type="text"/> | DOSE.ASST (HH24:MI) TMAD |
| SDV | * Dose Date | <input type="text"/> | DOSE.POA DDT |
| SDV | * Dose Time | <input type="text"/> : <input type="text"/> | DOSE.POA (HH24:MI) DTM |
| | Please check if time given is estimated time. | <input type="checkbox"/> | DOSE.STTM AEST |
| SDV | * Infusion rate (mg/hour) | <input type="text"/> | DOSE.INFR (format xxxx) TAD |
| SDV | * Did patient vomit/spit up within one hour of dosing? | <input type="radio"/> Yes <input type="radio"/> No | DOSE.ORE NTDSA |
| SDV | * What percentage of dose is estimated to have been vomited/spit up? | <input type="text"/> | DOSE.PERV (format xxx) OMAD |
| SDV | * Was patient re-dosed? | <input type="radio"/> Yes <input type="radio"/> No | DOSE.RED SADYN |
| SDV | * Dose Administered (mg) | <input type="text"/> | DOSE.RED (format xxx) OSEAD |
| SDV | * Re-dose Date | <input type="text"/> | DOSE.RED SADDT |
| SDV | * Re-dose Time | <input type="text"/> : <input type="text"/> | DOSE.RED (HH24:MI) SADTM |

| | | | |
|------------|-----------------------------------------------|-------------------------------------------------------|---------------------------------|
| | Please check if time given is estimated time. | <input type="checkbox"/> | DOSE.RED SAEST |
| SDV | * Dosing Interrupted? | <input type="radio"/> Yes <input type="radio"/> No | DOSE.INTR PTAD |
| SDV | * Interrupted Stop Date: | <input type="text"/> | DOSE.INTD TAD |
| SDV | * Interrupted Stop Time: | <input type="text"/> : <input type="text"/> | DOSE.INTT (HH24:MI) MAD |
| SDV | * Dosing Restarted? | <input type="radio"/> Yes <input type="radio"/> No | DOSE.REST RTAD |
| SDV | * Restarted Date: | <input type="text"/> | DOSE.RSTR DTAD |
| SDV | * Restarted Time: | <input type="text"/> : <input type="text"/> | DOSE.RSTR (HH24:MI) TMAD |
| SDV | * Infusion rate (mg/hour) | <input type="text"/> | DOSE.INFR (format xxxx) TREA |
| SDV | * Final Stop Date | <input type="text"/> | DOSE.FNSP DTAD |
| SDV | * Final Stop Time | <input type="text"/> : <input type="text"/> | DOSE.FNSP (HH24:MI) TMAD |

DOV

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DATE OF VISIT

* Date of visit



SV.SVDT




DS

Page

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| | | |
|------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| Did subject discontinue the study early? | <input type="radio"/> Yes <input type="radio"/> No | DS.DISCYN |
| * Date of Discontinuation | <input type="text"/>  | DS.DSSTDY |
| Reason for Discontinuation | <input type="radio"/> Adverse Event <input type="radio"/> Death <input type="radio"/> Lost to follow-up <input type="radio"/> Non-compliance With Study Drug <input type="radio"/> Physician Decision <input type="radio"/> Pregnancy <input type="radio"/> Protocol Violation <input type="radio"/> Study Terminated By Sponsor <input type="radio"/> Withdrew Assent <input type="radio"/> Study Subject Withdrawal by Parent or Guardian <input type="radio"/> Other | DS.DSTERM |

HLAB

Page

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| | | |
|----------------------------------------------------------|---------------------------------------------|--------------------------|
| Check box if labs were not done <input type="checkbox"/> | | HLAB.LLAB ND |
| Date and Time | | |
| * Lab date | <input type="text"/> | HLAB.LABD T |
| * Lab time | <input type="text"/> : <input type="text"/> | HLAB.LABT (HH24:MI) M |
| * Lab Name | <input type="text"/> | HLAB.LABN AME |
| Labs | | |

| Assessment | Yes/No | Same Date and Time | Date | Time | Value | Units | Results |
|----------------|--------------------------------------|--------------------------|----------------------|----------------------|------------------------------|------------------------------------------------|-----------------------------------------------|
| Hemoglobin | <input checked="" type="radio"/> Yes | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | (| (x | <input type="text"/> |
| | <input type="radio"/> No | | | | H H 2 4: M l) | x x x x x x x x x x | g/d L g/L |
| | HLAB .HGB ND | HLAB .HGB SM | HLAB .HGB DT | HLAB .HGB TM | HLAB .HGB VAL | HLAB .HGB UNIT | HLAB .HGB RSLT |
| Hematocrit | <input checked="" type="radio"/> Yes | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | (| (x | <input type="text"/> |
| | <input type="radio"/> No | | | | H H 2 4: M l) | x x x x x x x x x x | % Q/L |
| | HLAB .HCT ND | HLAB .HCT SM | HLAB .HCT DT | HLAB .HCT TM | HLAB .HCT VAL | HLAB .HCT UNIT | HLAB .HCT RSLT |
| Platelet Count | <input checked="" type="radio"/> Yes | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | (| (x | <input type="text"/> |
| | <input type="radio"/> No | | | | H H 2 4: M l) | x x x x x x x x x x | 10 ⁹ /L 10 ³ /μ L |
| | HLAB .PLT ND | HLAB .PLT SM | HLAB .PLT DT | HLAB .PLT TM | HLAB .PLT VAL | HLAB .PLT UNT | HLAB .PLT RSLT |

Please complete an AE form.

Please complete an AE form.

Please complete an AE form.

| | | | | | | | | |
|------------------------------|--------------|--------------------------|----------------------|------------------------------|------------------------------------------------|------------------------|-----------------------------|----------------------|
| White Blood Cell Count (WBC) | Yes | <input type="checkbox"/> | <input type="text"/> | (| (x | 10 | Please complete an AE form. | <input type="text"/> |
| | No | | | H H 2 4: M l) | x x x x x x x x x x | ^9/L m ³ | | |
| | HLAB .WBC ND | HLAB .WBC SM | HLAB .WBC DT | HLAB .WBC TM | HLAB .WBC VAL | HLAB .WBC UNT | | HLAB .WBC RSLT |


IE


Page

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| | | | |
|-----------------------------------|----------------------------------------------------------------------------------------|-------------------------------------------------------|-----------------|
| SDV | * Date Informed Consent signed by parent/guardian | <input type="text"/> | IE.GCONSD T |
| | Was assent signed by patient? | <input type="radio"/> Yes <input type="radio"/> No | IE.ASSENT YN |
| SDV | Date assent signed by patient | <input type="text"/> | IE.ASSENT DT |
| SDV | * Is patient eligible based upon inclusion/exclusion criteria? | <input type="radio"/> Yes <input type="radio"/> No | IE.IEMET |
| Inclusion Criteria Not Met | | | |
| | 1. Informed consent / assent | <input type="checkbox"/> | IE.INCNM1 |
| | 2. Prevention/treatment of confirmed/suspected infection | <input type="checkbox"/> | IE.INCNM2 |
| | 3. Postmenstrual age (PMA) >36 weeks | <input type="checkbox"/> | IE.INCNM3 |
| | 4. Able to take oral drugs (TMP-SMX) | <input type="checkbox"/> | IE.INCNM4 |
| | 5. Sufficient IV access for drug administration and/or sample collection | <input type="checkbox"/> | IE.INCNM5 |
| Exclusion Criteria Met | | | |
| | 1. Allergy | <input type="checkbox"/> | IE.EXCNM1 |
| | 2. For clindamycin, treatment with strong CYP3A4 inhibitors or inducers | <input type="checkbox"/> | IE.EXCNM2 |
| | 3. Serum creatinine >2 mg/dl within 48 hours prior to enrollment | <input type="checkbox"/> | IE.EXCNM3 |
| | 4. Known ALT >250 U/L or AST >500 U/L on measurement closest to the time of enrollment | <input type="checkbox"/> | IE.EXCNM4 |
| | 5. Known pregnancy | <input type="checkbox"/> | IE.EXCNM5 |
| | 6. Breastfeeding females | <input type="checkbox"/> | IE.EXCNM6 |
| | 7. On extracorporeal membrane oxygenation support | <input type="checkbox"/> | IE.EXCNM7 |

| | | | |
|------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| | 8. Any condition that, in the judgment of the investigator, precludes participation | <input type="checkbox"/> | IE.EXCNM8 |
| SDV | Was a waiver granted? | <input type="radio"/> Yes <input type="radio"/> No | IE.WAIVER |
| SDV | Date waiver granted | <input type="text"/>  | IE.WAVRDT |
| SDV | Name of person granting waiver | <input type="text"/> | IE.WVRAPP |
| | Has patient received study drug prior to enrollment per standard of care? | <input type="radio"/> No <input type="radio"/> Yes, patient received clindamycin. <input type="radio"/> Yes, patient received TMP-SMX. | IE.PRVDRG |



MH

Page

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| | | |
|---------------------------------------------------------------------------------------|-------------------------------------------------------|-----------------|
| <hr/> | | |
| * Has the subject experienced any past and/or concomitant diseases or past surgeries? | <input type="radio"/> Yes <input type="radio"/> No | MH.MHPRE F |
| * Body System | <input type="text"/> | MH.MHBOD SYS |
| Other specify | <input type="text"/> | MH.MHBOD SPC |
| * Condition/Event | <input type="text"/> | MH.MHTER M |
| * Start Date | <input type="text"/> | MH.MHSTD T |
| * Stop Date | <input type="text"/> | MH.MHEND T |
| Ongoing | <input type="radio"/> Ongoing | MH.MHONG |
| <hr/> | | |

OPPK

Page

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| | | |
|-----------------------------|--------------------------------------------------------------------------------------------------|---------------------------|
| * Date of sample collection | <input type="text"/> | OPPK.OPPK DT |
| * Time of sample collection | <input type="text"/> : <input type="text"/> | OPPK.OPPK (HH24:MI) TM |
| * Sample type | <input type="radio"/> Bone <input type="radio"/> Skin <input type="radio"/> Synovial fluid | OPPK.OPPK TYP |

PE

Page

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| | | |
|----------------------------------|----------------------|---------------------------|
| * Physical Exam Date | <input type="text"/> | PE.PEDT |
| * Height/length (in centimeters) | <input type="text"/> | PE.HEIGHT (format xxx.x) |
| * Actual weight (in kilograms) | <input type="text"/> | PE.WEIGHT (format xxx.xx) |

Enter results for each body system.

| Body System | Results | Specify: Abnormal Results |
|--------------------|----------------------|---------------------------|
| General Appearance | <input type="text"/> | <input type="text"/> |
| | PE.PEORRES | PE.PEDESC |
| Hair and Skin | <input type="text"/> | <input type="text"/> |
| | PE.PEORRES2 | PE.PEDESC2 |
| Lymphatics | <input type="text"/> | <input type="text"/> |
| | PE.PEORRES3 | PE.PEDESC3 |
| HEENT | <input type="text"/> | <input type="text"/> |
| | PE.PEORRES4 | PE.PEDESC4 |
| Respiratory | <input type="text"/> | <input type="text"/> |
| | PE.PEORRES5 | PE.PEDESC5 |
| Cardiovascular | <input type="text"/> | <input type="text"/> |
| | PE.PEORRES6 | PE.PEDESC6 |
| Abdominal | <input type="text"/> | <input type="text"/> |
| | PE.PEORRES7 | PE.PEDESC7 |
| Musculoskeletal | <input type="text"/> | <input type="text"/> |
| | PE.PEORRES8 | PE.PEDESC8 |
| Mental Status | <input type="text"/> | <input type="text"/> |
| | PE.PEORRES9 | PE.PEDESC9 |
| Neurological | <input type="text"/> | <input type="text"/> |
| | PE.PEORRES1 | PE.PEDESC1 |
| Endocrine | <input type="text"/> | <input type="text"/> |
| | PE.PEORRES1 1 | PE.PEDESC11 |
| Other | <input type="text"/> | <input type="text"/> |
| | PE.PEORRES9 8 | PE.PEDESC98 |

PRVDRG

Page

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*** How many doses of study drug did patient receive prior to enrollment?**

- 1 PRVDRG.P
- 2 RVDRGNU
- 3
- 4
- 5
- 6 or more

Most recent study drug administration prior to enrollment

| | | |
|--------------------------------|-------------------------------------------------------------------------------|----------------------------------|
| * Route | <input type="radio"/> IV <input type="radio"/> PO | PRVDRG.P RV1RT |
| * Type | <input type="radio"/> Capsules or tablets <input type="radio"/> Suspension | PRVDRG.P RV1TYP |
| * Date | <input type="text"/> | PRVDRG.P RV1DT |
| * Time | <input type="text"/> : <input type="text"/> | PRVDRG.P (HH24:MI) RV1TM |
| * Start date | <input type="text"/> | PRVDRG.P RV1STDT |
| * Start time | <input type="text"/> : <input type="text"/> | PRVDRG.P (HH24:MI) RV1STTM |
| * End date | <input type="text"/> | PRVDRG.P RV1ENDT |
| * End time | <input type="text"/> : <input type="text"/> | PRVDRG.P (HH24:MI) RV1ENTM |
| * Infusion rate (mg/hour) | <input type="text"/> | PRVDRG.IN (format xxxx) FRAT1 |
| * Total Dose Administered (mg) | <input type="text"/> | PRVDRG.T (format xxx) OTDS1 |

Second most recent study drug administration prior to enrollment

| | | |
|--------------|-------------------------------------------------------------------------------|-----------------------------|
| * Route | <input type="radio"/> IV <input type="radio"/> PO | PRVDRG.P RV2RT |
| * Type | <input type="radio"/> Capsules or tablets <input type="radio"/> Suspension | PRVDRG.P RV2TYP |
| * Date | <input type="text"/> | PRVDRG.P RV2DT |
| * Time | <input type="text"/> : <input type="text"/> | PRVDRG.P (HH24:MI) RV2TM |
| * Start date | <input type="text"/> | PRVDRG.P RV2STDT |

| | | | |
|-------------------------------------------------------------------------|-------------------------------------------------------------------------------|---------------------|---------------|
| * Start time | <input type="text"/> | PRVDRG.P RV2STTM | (HH24:MI) |
| * End date | <input type="text"/> | PRVDRG.P RV2ENDT | |
| * End time | <input type="text"/> | PRVDRG.P RV2ENTM | (HH24:MI) |
| * Infusion rate (mg/hour) | <input type="text"/> | PRVDRG.IN FRAT2 | (format xxxx) |
| * Total Dose Administered (mg) | <input type="text"/> | PRVDRG.T OTDS2 | (format xxx) |
| Third most recent study drug administration prior to enrollment | | | |
| * Route | <input type="radio"/> IV <input type="radio"/> PO | PRVDRG.P RV3RT | |
| * Type | <input type="radio"/> Capsules or tablets <input type="radio"/> Suspension | PRVDRG.P RV3TYP | |
| * Date | <input type="text"/> | PRVDRG.P RV3DT | |
| * Time | <input type="text"/> | PRVDRG.P RV3TM | (HH24:MI) |
| * Start date | <input type="text"/> | PRVDRG.P RV3STD | |
| * Start time | <input type="text"/> | PRVDRG.P RV3STTM | (HH24:MI) |
| * End date | <input type="text"/> | PRVDRG.P RV3ENDT | |
| * End time | <input type="text"/> | PRVDRG.P RV3ENTM | (HH24:MI) |
| * Infusion rate (mg/hour) | <input type="text"/> | PRVDRG.IN FRAT3 | (format xxxx) |
| * Total Dose Administered (mg) | <input type="text"/> | PRVDRG.T OTDS3 | (format xxx) |
| Fourth most recent study drug administration prior to enrollment | | | |
| * Route | <input type="radio"/> IV <input type="radio"/> PO | PRVDRG.P RV4RT | |
| * Type | <input type="radio"/> Capsules or tablets <input type="radio"/> Suspension | PRVDRG.P RV4TYP | |
| * Date | <input type="text"/> | PRVDRG.P RV4DT | |
| * Time | <input type="text"/> | PRVDRG.P RV4TM | (HH24:MI) |
| * Start date | <input type="text"/> | PRVDRG.P RV4STD | |
| * Start time | <input type="text"/> | PRVDRG.P RV4STTM | (HH24:MI) |
| * End date | <input type="text"/> | PRVDRG.P RV4ENDT | |
| * End time | <input type="text"/> | PRVDRG.P RV4ENTM | (HH24:MI) |

| | | |
|------------------------------------------------------------------------|-------------------------------------------------------------------------------|----------------------------------|
| * Infusion rate (mg/hour) | <input type="text"/> | PRVDRG.IN (format xxxx) FRAT4 |
| * Total Dose Administered (mg) | <input type="text"/> | PRVDRG.T (format xxx) OTDS4 |
| Fifth most recent study drug administration prior to enrollment | | |
| * Route | <input type="radio"/> IV <input type="radio"/> PO | PRVDRG.P RV5RT |
| * Type | <input type="radio"/> Capsules or tablets <input type="radio"/> Suspension | PRVDRG.P RV5TYP |
| * Date | <input type="text"/> | PRVDRG.P RV5DT |
| * Time | <input type="text"/> : <input type="text"/> | PRVDRG.P (HH24:MI) RV5TM |
| * Start date | <input type="text"/> | PRVDRG.P RV5STDT |
| * Start time | <input type="text"/> : <input type="text"/> | PRVDRG.P (HH24:MI) RV5STTM |
| * End date | <input type="text"/> | PRVDRG.P RV5ENDT |
| * End time | <input type="text"/> : <input type="text"/> | PRVDRG.P (HH24:MI) RV5ENTM |
| * Infusion rate (mg/hour) | <input type="text"/> | PRVDRG.IN (format xxxx) FRAT5 |
| * Total Dose Administered (mg) | <input type="text"/> | PRVDRG.T (format xxx) OTDS5 |
| Sixth most recent study drug administration prior to enrollment | | |
| * Route | <input type="radio"/> IV <input type="radio"/> PO | PRVDRG.P RV6RT |
| * Type | <input type="radio"/> Capsules or tablets <input type="radio"/> Suspension | PRVDRG.P RV6TYP |
| * Date | <input type="text"/> | PRVDRG.P RV6DT |
| * Time | <input type="text"/> : <input type="text"/> | PRVDRG.P (HH24:MI) RV6TM |
| * Start date | <input type="text"/> | PRVDRG.P RV6STDT |
| * Start time | <input type="text"/> : <input type="text"/> | PRVDRG.P (HH24:MI) RV6STTM |
| * End date | <input type="text"/> | PRVDRG.P RV6ENDT |
| * End time | <input type="text"/> : <input type="text"/> | PRVDRG.P (HH24:MI) RV6ENTM |
| * Infusion rate (mg/hour) | <input type="text"/> | PRVDRG.IN (format xxxx) FRAT6 |
| * Total Dose Administered (mg) | <input type="text"/> | PRVDRG.T (format xxx) OTDS6 |

PT

Page

(Visit ID = 265162, Page ID =)

Unique Identifier page-265162-265162-265162-

| | | |
|-----------------------------------------------|-----------------------------------------------------------------------------------------------|---------------------|
| * Was pregnancy test performed at this visit? | <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not Applicable | PT.PREGTS T |
| * Collection date | <input type="text"/> | PT.PGTSTD T |
| * Collection time | <input type="text"/> : <input type="text"/> | PT.PGTIME (HH24:MI) |
| * Result | <input type="radio"/> Positive <input type="radio"/> Negative | PT.PGPSNG |

SAECM

Page

(Visit ID = 265199, Page ID =)

Unique Identifier page-265199-265199-265199-

| | | | |
|---------------------------------------------------|--------------------------------|-------------------------------|------------------|
| <input type="checkbox"/> | | | AECM.CMN OT |
| Concomitant Medication Details page is not needed | | | |
| Concomitant Medication Details | | | |
| SDV | Medication Name | <input type="text"/> | AECM.MED NAM |
| SDV | Relevant Medication Start Date | <input type="text"/> | AECM.MED STDT |
| SDV | Relevant Medication Stop Date | <input type="text"/> | AECM.MED SPDT |
| SDV | Ongoing | <input type="radio"/> Ongoing | AECM.MED ONGO |
| SDV | Medication Total Daily Dose | <input type="text"/> | AECM.MED DOS |
| SDV | Unit | <input type="text"/> | AECM.MED UNIT |
| SDV | Indication | <input type="text"/> | AECM.MEDI ND |

SAELAB

Page

(Visit ID = 265200, Page ID =)

Unique Identifier page-265200-265200-265200-

| | | | |
|-----|-------------------------|---------------------------------------------|-------------------------------------------|
| | Lab Number | <input type="text"/> | LB.LBNUM |
| SDV | * Collection Date | <input type="text"/> | LB.LBDT |
| SDV | * Collection Time | <input type="text"/> : <input type="text"/> | LB.LBTM (HH24:MI) |
| SDV | * Test Name | <input type="text"/> | LB.LBTEST |
| SDV | Other Lab Test | <input type="text"/> | LB.LBTSTO TH |
| SDV | * Test Results | <input type="text"/> | LB.LBORRE S |
| SDV | * Units | <input type="text"/> | LB.LBORRE SU |
| SDV | * Lower Limit of Normal | <input type="text"/> | LB.LBORN RLO (format xxxxxxxxx.xxx) |
| SDV | * Upper Limit of Normal | <input type="text"/> | LB.LBORN RHI (format xxxxxxxxx.xxx) |

SAE_NARR

Page

(Visit ID = 265201, Page ID =)

Unique Identifier page-265201-265201-265201-

SAE Narrative page is not needed

AE_SAE.NA
RRNOT

SAE Narrative

Provide a narrative, in chronological order, of the clinical course of this SAE from onset through resolution. 1. Presenting signs and symptoms 2. Treatments and response to treatments 3. Subject's status at time of report and/or final outcome, as applicable

The field below contains a maximum of 200 characters. If additional space is needed to complete the narrative, place a checkmark in the checkbox next to "(Remain at this screen to add more)" which is under the "Add" button. Then click the "Add" button. Create as many copies of this page as needed to provide the complete narrative.

SAE Narrative

AE_SAE.NA
RSYMP

Is Narrative entry completed?

- Yes, narrative finished
- No, adding another narrative page

AE_SAE.NA
REND



SOCD

Page

(Visit ID = 265220, Page ID =)

Unique Identifier page-265220-265220-265220-

Microbiological Evaluations (record all cultures)

Record from within 48 hours prior to enrollment.

| | | |
|--------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| * Were any microbiologic assessments performed? | <input type="radio"/> Yes <input type="radio"/> No | SOCD.MICB |
| * Result | <input type="radio"/> Positive <input type="radio"/> Negative | SOCD.RES ULT |
| * Date | <input type="text"/> | SOCD.MICB DT |
| * Time | <input type="text"/> : <input type="text"/> | SOCD.MICB (HH24:MI) TM |
| * Type | <input type="radio"/> Blood culture <input type="radio"/> Urine culture (cath/clean catch only) <input type="radio"/> Cerebrospinal fluid culture (CSF) | SOCD.MICB TYP |
| * Species | <input type="radio"/> Bacteria <input type="radio"/> Fungi <input type="radio"/> Viruses <input type="radio"/> Parasites | SOCD.MICB SPC |
| * Organism | <input type="text"/> | SOCD.MICB ACT |
| * Organism | <input type="text"/> | SOCD.MICF NGI |
| * Organism | <input type="text"/> | SOCD.MICV RS |
| * Organism | <input type="text"/> | SOCD.MICP RA |
| * Other, specify | <input type="text"/> | SOCD.MICS PFY |

URINE

Page

(Visit ID = 265211, Page ID =)

Unique Identifier page-265211-265211-265211-

| Post Dose 6 (or last dose if dosing discontinued earlier) | | | |
|-----------------------------------------------------------|--------------------------------------------------|-------------------------------------------------------|------------------------------------|
| SDV | * Collection date | <input type="text"/> | PKU.PKUDT |
| SDV | * Collection time | <input type="text"/> : <input type="text"/> | PKU.PKUTM (HH24:MI) |
| SDV | * Sample accession number | <input type="text"/> | PKU.PKUAC (format xxxxxxxx) CNO |
| SDV | * Does patient wear diapers? | <input type="radio"/> Yes <input type="radio"/> No | PKU.PKUDI AP |
| SDV | * Volume (mL) | <input type="text"/> | PKU.PKUVO (format xxxxx) L |
| SDV | * Diaper weight (g) | <input type="text"/> | PKU.PKUDP (format xxx.xx) WT |
| SDV | * Date of previous urine output. | <input type="text"/> | PKU.PKUPR VDT |
| SDV | * Time of previous urine output. | <input type="text"/> : <input type="text"/> | PKU.PKUPR (HH24:MI) VTM |
| | Please check if time given is estimated time. | <input type="checkbox"/> | PKU.PKUES TTM |

URINE_2m

Page

(Visit ID = 418580, Page ID =)

Unique Identifier page-418580-418580-418580-

| | | | |
|-----------------------------------------------------------|--------------------------------------------------|-------------------------------------------------------|------------------------------------|
| Not Collected <input type="checkbox"/> | | | PKU.PKUNC |
| Post Dose 6 (or last dose if dosing discontinued earlier) | | | |
| SDV | * Collection date | <input type="text"/> | PKU.PKUDT |
| SDV | * Collection time | <input type="text"/> : <input type="text"/> | PKU.PKUTM (HH24:MI) |
| SDV | * Sample accession number | <input type="text"/> | PKU.PKUAC (format xxxxxxxx) CNO |
| SDV | * Does patient wear diapers? | <input type="radio"/> Yes <input type="radio"/> No | PKU.PKUDI AP |
| SDV | * Volume (mL) | <input type="text"/> | PKU.PKUVO (format xxxxx) L |
| SDV | * Diaper weight (g) | <input type="text"/> | PKU.PKUDP (format xxx.xx) WT |
| SDV | * Date of previous urine output. | <input type="text"/> | PKU.PKUPR VDT |
| SDV | * Time of previous urine output. | <input type="text"/> : <input type="text"/> | PKU.PKUPR (HH24:MI) VTM |
| | Please check if time given is estimated time. | <input type="checkbox"/> | PKU.PKUES TTM |