***Text in blue is for instruction only and should be deleted.***

***Text in black should be included if appropriate for the trial.***

**SOP Ref No *Insert trial title* Data Dictionary**

**Version *Insert number* 0.0**

**Date issued *Insert date* DDMMMYYYY**

**Valid until *Insert date* DDMMMYYYY**

**Author(s) Name:**

**Signature:**

**Date:**

**Approved by Name:**

**Signature:**

**Date:**

**Modification history**

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| **Version No** | **Date** | **Author(s)** | **Date reissued to previous recipients** |
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**RAPIDE TKM DATA REPOSITORY DICTIONARY**

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# Patient Level Data

# Patient Information

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Variable Name** | **Label** | **Type** | **Value** | **Definition** |
| SUBJID | Patient Identification Number | Text |  | Unique 6 digit patient identifier |
| COHORT | Cohort assigned | Category | X = X OBS= Observational | Treatment group patient was assigned to |
| CESTDAT | Day of onset of first/earliest symptom (number of minus days from admission) | Integer | 99 | Day on which first/earliest symptoms of EVD were reported (number of minus days from admission -Day 0 to the treatment centre. Study days = 0 -14 & 30) by the patient |
| SEX | Sex | Category | F=Female M=Male | Gender of the patient |
| AGE | Estimated age | Integer | 99 | Age of the patient |
| AGEU | Age Unit | Category | months=months (<2 years) years=years | Age units (months or years) |
| WEIGHT | Weight (Kg) | Integer | 999 | Weight of the patient |
| MBDAT | Study day on which malaria test was done | Integer | 99 | Study day on which malaria test was done |
| MBORRES | Malaria Result | Category | NEGATIVE=Negative POSITIVE=Positive UNKNOWN=Unknown NOTDONE=Not done | Result of malaria (RDT) test |
| SSORRES | Status at last contact | Category | ALAD=Alive admitted ALDIS=Alive discharged DEC=Deceased NOCONTACT=Unknown due to lack of contact WTHDRW=Unknown due to withdrawal of consent | Status of the patient when last contacted by trial staff |
| SSDAT | Last study day on which contact was made with patient | Integer | 99 | Study day on which contact was last made with the patient, by trial staff  |
| DSSTDAT | Study day on which patient died | Integer | 99 | Study day on which patient died  |
| DSSTCAU | Cause of death | Category | X=X UNK=Unknown OTH=Other | What was the cause of the patients death?IF other: specify |
| DSSTDAT | Study day on which patient achieved discharge criteria  | Integer | 99 | Study day on which contact was last made with the patient, by trial staff  |

# Daily Signs and Symptoms

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Variable Name** | **Label** | **Type** | **Value** | **Definition** |
| SUBJID | Patient Identification Number | Text |  | Unique 6 digit patient identifier |
| VISIT | Number of days since admission | Integer | 99 | Number of days since the patient was admitted to the treatment centre |
| VSPERF | Is data available for daily signs and symptoms? | Category | Y=Yes N=No | Was data available for daily signs and symptoms? |
| VSTPT | Assessment time point | Category | DAILY=Daily - SCRE = ScreeningPRE=Pre-infusionDUR=During infusionEND=End of infusion (0 hours)POST1=1 hour post infusionPOST2=2 hours post infusionPOST4=4 hours post infusionPOST8=8 hours post infusionOTH=Other | Time point when patient assessments were completed. |
| VSTIM | Time of assessment | Date/Time | hh:mm | Time assessments were completed |
| VSTEST | Sign or Symptom | Integer | MAXTEMP = Temperature (°C) at time of assessmentHR= Heart Rate (Beats per minute)RR = Respiratory rate (Breaths per minute)SYSBP = Systolic Blood Pressure (mmHg)DIABP = Diastolic Blood Pressure (mmHg) | Vital signs reported  |
| VSORRES | Value | Integer | 9999.9999 | Reported vital signs values |

# PCRs and qPCRs

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Variable Name** | **Label** | **Type** | **Value** | **Definition** |
| SUBJID | Patient Identification Number | Text |  | Unique 6 letter study identifier |
| VISIT | Number of days since admission | Integer | 99 | Number of days since the patient was admitted to the treatment centre |
| MBTIM | PCR sample collection time | Date/Time  | hh:mm | Time sample was taken |
| MBREFIDO | Sample Number | Integer | 9 | Sample number |
| MBORRES | Result | Category | NEGATIVE= Negative POSITIVE=Positive UNKNOWN=Unknown | PCR result |
| CTVALUE | CT Value | Real | 99.99 |  CT value |

# Study Drug Infusion

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Variable Name** | **Label** | **Type** | **Value** | **Definition** |
| SUBJID | Patient Identification Number | Text |  | Unique 6 digit patient identifier |
| VISIT | Number of days since admission | Integer | 99 | Number of days since the patient was admitted to the treatment centre |
| ECSPID | Dose number | Integer | 9 | Dose number |
| ECDSTXT | Dosage | Real  | 9.99 | Total infusion dose given |
| ECADJ | Dose adjustment reason | Category | REACT=Infusion related reaction OTH=Other | Reason for dose adjustmentIF Other: specify |
| ECTTIM | Start time of infusion | Date/Time | hh:mm | Time infusion was started |
| ECENTIM | Stop time of infusion | Date/Time | hh:mm | Time infusion was stopped |
| ECDSINTRP | Any drug interruptions | Category | Y=Yes N=No | Were there any infusion interruptions? |
| ECINTRP | Infusion interruption reason | Category | LINEOCC=Line occlusion IVLOSS= Loss of IV access REFUSE=Patient refused to continue PUMP=Pump failure REACT=Infusion related reaction OTH=Other | Reason given for infusion interruption |
| ECINTOTH | Infusion interruption other reason | Text |  | Other reason for interruption  |

1. Daily Non Study Medication

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Variable Name** | **Label** | **Type** | **Value** | **Definition** |
| SUBJID | Patient Identification Number | Text |   | Unique 6 digit patient identifier |
| VISIT | Number of days since admission | Integer | 99 | Number of days since the patient was admitted to the treatment centre |
| CMTRT | Product | Category | ALB=Albendazole CEFX=Cefixime COA=Coartem LOP=Loperamide METCL=Metoclopramide MUL=Multivit OME=Omeprazole PAR=Paracetamol POT=Potassium chloride OTH=Other RIN=Ringer's lactate DEX5=Dextrose 5% DEX10=Dextrose 10% DEX50=Dextrose 50% METROZ=Metronidazole MGCL=Magnesium chloride NACL=Normal Saline (NaCL) GEL=Gelofusine CEFTRI=Ceftriaxone TRAM=Tramadol MORPH=Morphine CHLPZ=Chlorpromazine PROMTHZ=Promethazine IVM=Ivermectin VITA=Vitamin A ART\_AMO=Artesunate/Amodiaquine AZITH=Azithromycin CPFLX=Ciprofloxacin AMOX=Amoxicillin ART=Artesunate ARTM=Arthemether HAL=Haloperidol DIAZ=Diazepam ZINC=Zinc Sulphate | Name of the products or medication administered |
| CMDSTXT | Dose | Real | 9.9 |  |
|  |  |  |  | Total dose of products or medication given |
| CMDOSU | Units | Category | mg=mg g=g tabs=Tablets ml=ml iu=iu mmol=mmol OTH=Other mcg=mcg | Dose units |
| CMROUTE | Route of administration | Category | IV=IV Oral=Oral Inhaled=Inhaled Other=Other Unknown=Unknown Rectum=Per rectum |  Route of administration |

1. Laboratory Results

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Variable Name** | **Label** | **Type** | **Values** | **Definition** |
| SUBJID | Patient Identification Number | Text  |  | Unique 6 digit patient identifier |
| VISIT | Number of days since admission | Integer | 99 | Number of days since the patient was admitted to the treatment centre |
| LBTEST | Test | Category | SODIUM= Sodium K =PotassiumBUN= Blood Urea NitrogenCL= ChlorideCREAT= Creatinine ALT= ALT/SGPTAST= AST/SGOTALP = Alkaline PhosphataseALB = AlbuminBILI= BilirubinTOTP=Total Protein CA = CalciumMAGNESIUM=MagnesiumGLUC = GlucoseTCO2 = Total CO2CK = Creatine KinaseCKMB = Creatine Kinase MBPHOSPHATE = PhosphateCRP = C-reactive proteinHGB = HaemoglobinHCT = HaematocritMCV = MCVWBC = WBCLYMP = LymphocytesMONO = MonocytesGRAN = Granulocytes RBC = RBCPLT = PlateletsAPTT = APTTPT = PTINR = INR | Laboratory test |
|  LBORRES | Result | Real | 9.9, 99, 99.9, 999.9 or 9999.9 | Laboratory test result |
| LBORRESU | Unit |  Category | mEq/LU/L%mmol/L103/mm3 mg/dL mg/Lμm3mmol/L umol/L g/dLg/L10^3/UL                                           10^9/LSeconds | Laboratory test units |