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TEMPLATE: Case Record Form for Visceral Leishmaniasis and HIV co-infection

Annotated Case Record Form (aCRF) for use in clinical trials in patients with

Visceral Leishmaniasis (VL) and HIV co-infection

Version 1.0, June 2023

**INSTRUCTION & CONTENTS PAGE**

This Case Record Form template is intended as a guide and may be tailored to collect the data required by the clinical research protocol to answer the specific research question being addressed. It is intended for participants who meet the enrolment criteria as specified in inclusion/exclusion criteria of the study protocol; Clinical Data Acquisition Standards Harmonization (CDASH) annotations are included in blue; Standard Data Tabulation Module (SDTM) in red. Trial sites can select which modules to include in their CRF based on protocol requirements; modules included in the following CRF are below:

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|  | **DATA MODULE** |
| **DAY -7 to DAY /VISIT1**  | Eligibility assessment and randomisation |
| HIV diagnosis, history and ART  |
| Current episode and previous treatment for VL |
| Current episode and previous treatment for PKDL |
| Pregnancy testing |
| ECG recording |
| Demographics |
| Past medical history  |
| Medical history (includes signs and symptoms and concomitant acute illness) |
| Clinical examination and vital signs |
| **VISIT 1 & FOLLOW-UP DAYS****[[1]](#footnote-1)** | Laboratory results, including pregnancy |
|  | Microbiology results |
|  | Tuberculosis examination |
|  | Concomitant disease diagnostics |
|  | Parasitological examination |
|  | Study drug administration |
|  | Rescue medication |
|  | Adverse events, serious adverse events and medically attended adverse events  |
|  | Concomitant medications |
|  | Efficacy assessment (includes clinical and parasitological response)  |
| **DISPOSITION**  | OR Reason for non-completion of study |
| Detailed pregnancy assessment |
| **APPENDICES**  | 1. Detailed Pregnancy Assessment
 |
| 1. Audiometric examination
 |
| 1. Pharmacokinetic sampling
 |
| 1. Radiology testing
 |
| 1. G6PD testing
 |
| 1. Ophthalmic Examination
 |
| **SCREENING VISIT (Day -7 to Day 1)** |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]****VISDAT** |
| **Date informed consent given****DSDECOD=INFORMED CONSENT****DSCAT DSTERM = “PROTOCOL MILESTONE”** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]****DSSTDAT** **DSSTDTC RFICDTC** |
| **Date of screening****VISDAT** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]****IEDAT IEDTC** |
| ELIGIBILITY ASSESSMENT **[IE]** |
| Inclusion CriteriaIETESTCD (IECAT= INCLUSION)  | **Criterion Description****[Adapt as per protocol] IETEST** | **Yes** | **No** |
| **IEORRES** |
| INCL001 | Patients for whom written informed consent has been obtained (if aged 18 years and over) or signed by parents(s) or legal guardian for patients under 18 years of age. In the case of minors, assent from the children also needs to be obtained as per each country regulatory requirements. | **€** | **€** |
| INCL002 | Patients confirmed HIV positive (2 rapid diagnostics tests (RDTs)) as per National AIDS programme guidelines, Western Blot for any discrepancy. | **€** | **€** |
| INCL003 | Patients with clinical signs and symptoms of VL and confirmatory parasitological microscopic diagnosis or equivalent, as defined in the protocol. | **€** | **€** |
| Exclusion Criteria**IETESTCD (IECAT= EXCLUSION)**  | **Criterion Description****[Adapt as per protocol] IETEST** | **Yes** | **No** |
| **IEORRES** |
| EXCL001 | Women of child-bearing potential who are not using an assured method of contraception or are unwilling to use an assured method of contraception for the duration of treatment and (xx) months after as defined in the protocol. | **€** | **€** |
| EXCL002 | Breast-feeding women. | **€** | **€** |
| EXCL003 | Pregnant women. | **€** | **€** |
| EXCL004 | Patients who have received any anti-leishmanial drugs in the last [xx] months as defined in the protocol. | **€** | **€** |
| EXCL005 | Patients with previous history of hypersensitivity reaction or known drug class allergy to any of the study treatments. | **€** | **€** |
| EXCL006 | Concomitant severe infection or other serious underlying disease that would preclude evaluation of patients’ response to study medication as defined in the protocol. | **€** | **€** |
| **Assessment of eligibility at VISIT 1** | **Yes** | **No** |
| **Did the subject meet all eligibility criteria? IEYN** | **€** | **€** |
| RANDOMISATION **[DS]** |
| **Date of randomisation** **DSTERM (DSDECOD = RANDOMIZATION)****DSCAT = PROTOCOL MILESTONE** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]****DSSTDAT DSSTDTC** |
| If applicable, to which group is participant randomised? **ARM ARMCD** |  |

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| CURRENT EPISODE & PREVIOUS TREATMENT FOR HIV **MHCAT = GENERAL MHSCAT = “HIV”** |
| **Does the patient have an established diagnosis of HIV?**  **MHTERM = “HIV”, MHPRESP= “Y”, MHOCCUR** | € Yes | € No | € Don’t know | **If yes, referral by ART centre:****HOYN, HOCAT = “ART”** | € Yes | € No |
| **If yes, ART centre name:****HOSPID** |  | Date of HIV diagnosis:MHDAT MHDTC | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY] |
| **On ART?****CMCAT,**  **CMTRT = “ART”,**  **CMPRESP = “Y”,** **CMOCCUR** | € Yes | € Never started | € Discontinued ART | ART start date:CMSTDAT CMSTDTC | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY] |
| **ART number (allocated by MoH) CMSPID** |  | Previous ART regimen: CMTRT where CMCAT = “MEDICAL HISTORY” |  |
| **Reason for change in ART regimen (if known):**   **CMADJ** |  | Current ART regimen: ECTRT, ECDSTXT, ECDOSU ECDOSTXT/ECDOSE |  |
| **Number of days ART doses were missed in the last month**  | € None€ 1-7€ 8-14€ > 14€ UNK[[2]](#footnote-2) | Remark on adherence: COVAL CO.COVAL |  |
| Was secondary prophylaxis givenCMPRESP = “Y”, CMOCCUR | € Yes € No | Secondary prophylaxisCMTRT | € Co-trimoxazole € Other |
| Other, specify:CMTRT |  |
| CD4 counts (10^6/L)[[3]](#footnote-3) [[4]](#footnote-4) CD4\_LBORRESU | Viral load in (RNA copies/ml)[[5]](#footnote-5) MBORRESU |
| CD4 – 1:LBORRES  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY] LBDAT LBDTC | VL – 1:MBORRES | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY] MBDAT MBDTC |
| CD4 – 2: LBORRES  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY] LBDAT LBDTC | VL – 2:MBORRES | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY] MBDAT MBDTC |
| CD4 – 3: LBORRES  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY] LBDAT LBDTC | VL – 3:MBORRES | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY] MBDAT MBDTC |
| CD4 – 4: LBORRES  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY] LBDAT LBDTC | VL – 4:MBORRES | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY] MBDAT MBDTC |
| *To be considered part of medical history and prior concomitant medications; details of previous HIV diagnosis to be included in the MH domain and details of previous treatments for HIV to be included in the CM domain*  |

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| CURRENT EPISODE & PREVIOUS TREATMENT FOR VL MHCAT = GENERAL MHSCAT = “VL” |
| **Type of VL at presentation If Relapse = “Y” – RSORRES = Relapse where RSTESTCD = “OVRLRESP”, RSCAT = “VL” and RSSCAT = “MEDICAL HISTORY”** | € Primary | € Relapse | **How many previous episodes has the subject experienced? AEPATT where AETERM =”Previous VL episodes”** |  |
| **Date of first episode of VL MHSTDAT MHSTDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY] | Treatment received for first episode of VL CMTRTCMCAT = “MEDICAL HISTORY” |  |
| **Number of previous treatments (including treatment for first episode)? MHPATT** |  | Are previous treatment regimens known? CMPRIOR CMYN | € Yes | € No | € NA |
| **Start date****CMSTDAT CMSTDTC** | Treatment Given CMTRT | Treatment Response [RS]RSORRES where RSTEST = “Overall Response”, RSCAT = “VL” and RSSCAT = “MEDICAL HISTORY” | **End date**CMENDAT CMENDTC | Or ongoing? CMONGO MHENRTPT/MHENRF |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY]  |  | € Cure € Failure€ Failure - Relapse | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY] | € |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY]  |  | € Cure € Failure€ Failure - Relapse | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY] | € |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY]  |  | € Cure € Failure€ Failure - Relapse | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY] | € |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY]  |  | € Cure € Failure€ Failure - Relapse | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY] | € |
| Was secondary prophylaxis given CMPRESP = “Y”, CMOCCUR | € Yes € No | Was more than one secondary prophylaxis given in the past? CMPRESP = “Y”, CMOCCUR | € Yes € No |
| **Start date CMSTDAT CMSTDTC** | Treatment Given CMTRT | **Frequency[[6]](#footnote-6) CMDOSFRQ** | **Dose formulation CMDOSFRM** | **Dose amount CMDOSE** | **Unit**CMDOSU | Route of administration[[7]](#footnote-7)CMROUTE | End date CMENDAT CMENDTC | Reason for discontinuation of drug CMRSDISC  |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]** | € Pentamidine Isethionate € Liposomal Amphotericin B € Amphotericin B Deoxycholate € Miltefosine€ Paromomycin€ Other | **€** QD**€** QM | **€** tablet**€** capsule**€** susp.**€** injection |  | € mg/kg€ mL€ mg€ TABLETS | € PO€ IM€ IV | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY] |  |
| Other, specify: |  |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]** | € Pentamidine Isethionate € Liposomal Amphotericin B € Amphotericin B Deoxycholate € Miltefosine€ Paromomycin€ Other | **€** QD**€** QM | **€** tablet**€** capsule**€** susp.**€** injection |  | € mg/kg€ mL€ mg**€** TABLETS | € PO€ IM€ IV | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY] |  |
| Other, specify: |  |
| *To be considered part of medical history and prior concomitant medications; details of previous VL diagnosis to be included in the MH domain and details of previous treatments for VL to be included in the CM domain* |

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| CURRENT EPISODE & PREVIOUS TREATMENT FOR PKDL MHCAT = GENERAL MHSCAT = “PKDL” |
| Has the subject been previously diagnosed with PKDL? MHPRESP = “Y”, MHTERM = “PKDL”, MHOCCUR  | € Yes | € No | If yes, number of previous treatments? MHPATT |  |
| Are previous treatment regimens known? CMPRIOR CMYN | € Yes | € No |  |
| PKDL at baseline MHOCCUR | € Yes | € No | Type of PKDL at presentation If Relapse = “Y” - RSORRES = Relapse where RSTESTCD = “OVRLRESP” RSCAT = “PKDL” and RSSCAT = “MEDICAL HISTORY” | € Primary | € Relapse |
| If yes, indicate the PKDL severity/grade[[8]](#footnote-8) PESEV  | € Mild[[9]](#footnote-9) | € Moderate[[10]](#footnote-10) | € Severe[[11]](#footnote-11) |
| **Date of onset of PKDL**MHSTDAT MHSTDTC | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY] | **Type of skin lesions**PEORRES | **€** Macular**€** Papular**€** Nodular**€** Mucosal€ Mixed |
| *To be considered part of medical history and prior concomitant medications; details of previous PKDL diagnosis to be included in the MH domain and details of previous treatments for PKDL to be included in the CM domain* |

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| PREGNANCY TESTING[[12]](#footnote-12) **LBCAT=PREGNANCY *Only applicable to women of child-bearing potential, as defined in the protocol*** |
| **Was a sample taken for pregnancy testing?** **LBPERF LBSTAT** | **€** Yes  | **€** No  | **€** NA[[13]](#footnote-13) | **Specimen type****LBSPEC** | **€** Urine**€** Blood   | **Date of sample collection LBDAT LBDTC** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY]**  |
| **Pregnancy test name****LBTEST** | **Not done****LBPERF LBSTAT** | **Reason not done****LBREASND** | **Result LBORRES** |
|  | **€** | € Pre-menarche€ Permanently sterile[[14]](#footnote-14)€ Postmenopausal€ Refused test€ Other, specify below | € Negative | € Positive |
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| ECG RECORDING **[EG]** | *If the ECG is to be taken more than once at a study time-point (EG. Triple ECG), record ECG number EG ECG1, ECG2 etc. and repeat ECG module for each recording and the final result for analysis* |
| **Was the ECG recorded?****EGPERF EGSTAT [[15]](#footnote-15)**  | **€** Yes  | **€** No | **If not done, give reason EGREASND** |  | **Method EGMETHOD** | **€** Standard12 Lead **12-LEAD STANDARD** **EGLEAD** |
| **Number of ECG PRPATT where PRTRT= ”ECG”** | **Date ECG recorded** **EGDAT EGDTC** | **Time ECG recorded****EGTIM EGDTC** |
|  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** | |\_\_|\_\_|:|\_\_|\_\_|**[HH:MM]** |
| **ECG TEST RESULTS** |
| **ECG test name****EGTEST** | **Results****EGORRES** | **Units[[16]](#footnote-16)****EGORRESU** | **Not done****EGPERF EGSTAT** | **Reason not done****EGREASND** |
| **RR-interval**  | **|\_\_|\_\_|\_\_|\_\_| RRMEAN\_EGORRES** | MSEC | **€** |  |
| **PR-interval**  | **|\_\_|\_\_|\_\_| PRMEAN\_EGORRES** | MSEC | **€** |  |
| **QT-interval[[17]](#footnote-17)**  | **|\_\_|\_\_|\_\_| QTMEAN\_EGORRES** | MSEC | **€** |  |
| **QRS-duration**  | **|\_\_|\_\_|\_\_| QRSDUR\_EGORRES** | MSEC | **€** |  |
| **Supraventricular Arrhythmias** |  |  | **€** |  |
| **Supraventricular Tachyarrhythmias** |  |  | **€** |  |
| **Ventricular Arrhythmias** |  |  | **€** |  |
| **Ventricular Tachyarrhythmias** |  |  | **€** |  |

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| **Overall ECG Results EGORRES** | **€** Normal | **€** Abnormal | **If Abnormal, Was the ECG clinically Significant? EGCLSIG** | **€** Yes | **€** No |

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| DEMOGRAPHICS **[DM]** |
| **Date of completion****VISDAT** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|[DD-MMM-YYYY] DMDAT DMDTC | Time of completion | |\_\_|\_\_|:|\_\_|\_\_|[HH:MM] VISTIM DMDTC |
| **What is the subject’s date of birth?[[18]](#footnote-18) [[19]](#footnote-19) BRTHDAT BRTHDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| |
| **OR, if BRTHDAT unknown,** **what is the subject’s age?[[20]](#footnote-20) AGE** | |\_\_|\_\_|\_\_| | €Weeks | € Months | € Years |
| AGEU |
| **What is the sex of the subject?****SEX** | **€** Male | **€** Female | **€** Undifferentiated | **€** Unknown |
| **What is the race of the subject****[[21]](#footnote-21)?****CRACE[[22]](#footnote-22) RACE** | **€** Black **€** White**€** Asian Indian **€** Asian**€** Other |
| **If other, specify** **RACEOTH** |  |
| **What is the ethnicity of the subject? ETHNIC** | **€** Eastern Africa**€** South Asia **€** Latin America **€** Unknown **€** Other (specify below) |
| **If other, specify** **ETHNICOTH** |  |

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| MEDICAL HISTORY**MHCAT=General MHSCAT = “Surgery”** |
| **Does the patient have any clinically significant surgical history?** **MHYN[[23]](#footnote-23)** If yes, record below | **€** Yes | **€** No |
| **What is the term for the past surgical procedure?****MHTERM** | **Estimated start date[[24]](#footnote-24) MHSTDAT MHSTDTC** | **Estimated end date MHENDAT MHENDTC** | **Or ongoing? MHONGO MHENRTPT/MHENRF** |
|  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** | **€** |
|  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** | **€** |
| **Has the subject experienced any concomitant illness prior to screening?** **MHYN****MHSCAT = “Illness”** | € Yes | € No |
| **What is the term for the condition? [[25]](#footnote-25)****MHTERM**  | **Yes** | **No** | **If yes, give duration; if ongoing give number of days/weeks since start of symptom** | **Or ongoing?**  | **Toxicity Grade[[26]](#footnote-26)** **MHSEV** |
| **MHOCCUR** | **MHCDUR MHDUR** | **MHCDURU MHDURU** | **MHONGO MHENRTPT/MHENRF** |
| **Malaria** | **€** | **€** |  | **€** Days  | **€** Weeks  | **€** Months  | **€** | **€** Mild | **€** Moderate | **€** Severe |
| **Tuberculosis** | **€** | **€** |  | **€** Days  | **€** Weeks  | **€** Months  | **€** | **€** Mild | **€** Moderate | **€** Severe |
| **Hepatitis C** | **€** | **€** |  | **€** Days  | **€** Weeks  | **€** Months  | **€** | **€** Mild | **€** Moderate | **€** Severe |
| **Hepatitis B** | **€** | **€** |  | **€** Days  | **€** Weeks  | **€** Months  | **€** | **€** Mild | **€** Moderate | **€** Severe |
| **Other illness, specify** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **€** | **€** |  | **€** Days  | **€** Weeks  | **€** Months  | **€** | **€** Mild | **€** Moderate | **€** Severe |
| **Other illness, specify** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **€** | **€** |  | **€** Days  | **€** Weeks  | **€** Months  | **€** | **€** Mild | **€** Moderate | **€** Severe |
| PREVIOUS MEDICATION |
| **Were any medications taken within the last** (xx) days[[27]](#footnote-27)? The variable EVLINT is used to represent “within the last “xx” days” CMYN | € Yes | € No |
| ***If yes, record on the concomitant medications page (record full trade or generic names)*** |

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| VL SYMPTOMS ON MEDICAL HISTORY[[28]](#footnote-28) **MHCAT=General, MHSCAT = “VL Symptoms”** |
| **Did the subject have any of the following signs or symptoms within the last (xx) days? MHYN The variable EVLINT is used to represent “within the last “xx” days”** | € Yes | € No |
| **Symptom MHTERM**  | **Yes** | **No** | **If yes, give duration; if ongoing give number of days/weeks since start of symptom** | **Or ongoing**  | **Severity/intensity**  |
| **MHOCCUR** | **MHCDUR MHDUR** | **MHCDURU MHDUR** | **MHONGO MHENRTPT;** **MHENRF;** | **MHSEV[[29]](#footnote-29)**  |
| Fever | **€** | **€** |  | **€** Days  | **€** Weeks | **€** Months | **€** | **€** Mild | **€** Moderate | **€** Severe |
| Weight Loss | **€** | **€** |  | **€** Days  | **€** Weeks | **€** Months | **€** | **€** Mild | **€** Moderate | **€** Severe |
| Abdominal pain/discomfort | **€** | **€** |  | **€** Days  | **€** Weeks | **€** Months | **€** | **€** Mild | **€** Moderate | **€** Severe |
| Jaundice | **€** | **€** |  | **€** Days  | **€** Weeks | **€** Months | **€** | **€** Mild | **€** Moderate | **€** Severe |
| Oedema | **€** | **€** |  | **€** Days  | **€** Weeks | **€** Months | **€** | **€** Mild | **€** Moderate | **€** Severe |
| Epistaxis | **€** | **€** |  | **€** Days  | **€** Weeks | **€** Months | **€** | **€** Mild | **€** Moderate | **€** Severe |
| Other bleeding signs | **€** | **€** |  | **€** Days  | **€** Weeks | **€** Months | **€** | **€** Mild | **€** Moderate | **€** Severe |
| Diarrhoea | **€** | **€** |  | **€** Days  | **€** Weeks | **€** Months | **€** | **€** Mild | **€** Moderate | **€** Severe |
| Other symptoms | **€** | **€** |  | **€** Days  | **€** Weeks | **€** Months | **€** | **€** Mild | **€** Moderate | **€** Severe |
| If other, specify |  |

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| CLINICAL EXAMINATION **VS** |
| **Date examination taken VSDAT VSDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]** |
| **Clinical examination measurements VSTEST** | **Results VSORRES** | **Method of measurement/ Units VSORRESU** |
| Weight **WEIGHT\_VSTESTCD** | |\_\_|\_\_|\_\_|.|\_\_| **WEIGHT\_VSORRES** | kg **WEIGHT\_VSORRESU** |
| Weight-for-age z-score[[30]](#footnote-30) | |\_\_|.|\_\_| **WAZ\_VSORRES** | **€** WHOgrowth standards **VSMETHOD** |
| Height **HEIGHT\_VSTESTCD** | |\_\_|\_\_|\_\_|.|\_\_| **HEIGHT\_VSORRES** | cm **HEIGHT\_VSORRESU** |
| Height-for-age z-score | |\_\_|.|\_\_| **HAZ\_VSORRES** | **€** WHOgrowth standards **VSMETHOD** |
| Mid-Upper Arm Circumference **MUARMCIR\_VSTESTCD** | |\_\_|\_\_||\_\_| **MUAC\_VSORRES** | mm **MUAC\_VSORRESU** |
| Body Mass Index **BMI\_VSTESTCD** | |\_\_|\_\_|.|\_\_| **BMI\_VSORRES** | kg/m2 **BMI\_VSORRESU** |
| Malnutrition[[31]](#footnote-31) **AETERM, AEOCCUR** | **€** Yes  | **€** No | **€** z score <-2 (ref. WHOgrowth standards) |
| Severe malnutrition **AETERM, AEOCCUR** | **€ Y**es  | **€** No | **€** z score <-3 (ref. WHOgrowth standards) |
| Temperature **TEMP\_VSTESTCD**  | |\_\_|\_\_|.|\_\_|**TEMP\_VSORRES** | **€** °C **€** °FUnits **TEMP\_VSORRESU** | Method **VSMETHOD** | **€** Oral **€** Tympanic**€** Axillary**€** Rectal |
| Systolic blood pressure **SYSBP\_VSTESTCD** | **Result VSORRES** | **Position** **VSPOS** | **Units VSORRESU** |
| **|\_\_|\_\_|\_\_|** **SYSBP\_VSORRES** | **€** Supine | **€** Standing | **€** Sitting | mmHg **SYSBP\_VSORRESU** |
| Diastolic blood pressure **DIABP\_VSTESTCD** | **|\_\_|\_\_|\_\_| DIABP\_VSORRES** | **€** Supine | **€** Standing | **€** Sitting | mmHg **DIABP\_VSORRESU** |
| Pulse Rate **PULSE\_VSTESTCD** | **|\_\_|\_\_|\_\_| PULSE\_VSORRES** | **€** Supine | **€** Standing | **€** Sitting | beats/minute **PULSE\_VSORRESU** |
| Respiratory Rate **RESP\_VSTESTCD** | **|\_\_|\_\_| RESP\_VSORRES** | **€** Supine | **€** Standing | **€** Sitting | breaths/minute **RESP\_VSORRESU** |
| Oxygen Saturation **OXYSAT\_VSTESTCD** | **|\_\_|\_\_| OXYSAT\_VSORRES** | **€** Supine | **€** Standing | **€** Sitting | % **OXYSAT\_VSORRESU** |

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| **Examination MOLOC** | **Result MOORRES** |  | **Method MOMETHOD** |
| Spleen Size **SPLEEN\_MOTEST=LENGTH where MOLOC=SPLEEN** | **|\_\_|\_\_|.|\_\_|****SPLEEN\_MOORRES** | **cm SPLEEN\_MOORRESU** | **€** Ultra-sound **SPLEEN\_MOMETHOD** | **€** Manual palpation  | **€** Other method, if yes specify below**SPLEEN\_MOMETHODOTH** |
|  |
| Liver Size **LIVER\_MOTEST=LENGTH where MOLOC=LIVER** | **|\_\_|\_\_|.|\_\_|****LIVER\_MOORRES** | **cm LIVER\_MOORRESU** | **€** Ultra-sound **LIVER\_MOMETHOD** | **€** Manual palpation  | **€** Other method, if yes specify below**LIVER\_MOMETHODOTH** |
|  |
| Lymphadenopathy present **PEOCCUR where PETEST = LYMPHNODE ASSESSMENT** | If yes, give location **PELOC** |  | Other, specify **SPECOTH\_LYMPHNODE\_PELOC** |
| **€ Y**es  | **€** No | **€** Axillary**AXILLARY LYMPHNODE\_PELOC** | **€** Cervical**CERVICAL LYMPHNODE\_PELOC** | **€** Inguinal**INGUINAL LYMPHNODE\_PELOC** | **€** Other**OTHER\_LYMPHNODE\_PELOC** |  |
| If lymphadenopathy present give location | **€** Left**€** Right **€** Bilateral **AXILLARY LYMPHNODE\_PELAT** | **€** Left**€** Right **€** Bilateral **CERVICAL LYMPHNODE\_PELAT** | **€** Left**€** Right **€** Bilateral **INGUINAL LYMPHNODE\_PELAT** |  | **€** Left**€** Right **€** Bilateral **OTHER\_LYMPHNODE\_PELAT** |

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| **Other significant systemic findings such as HEENT, cardiovascular, respiratory, abdominal, skin, musculoskeletal? If yes specify below MHYN** | **€ Y**es  | **€** No |
| **What is the term for the medical history condition/event? MHTERM** | **Start date[[32]](#footnote-32)** **MHSTDAT MHSTDTC** |
|  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]** |
|  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]** |
|  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]** |
|  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]** |

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| **SCHEDULED VISITS (Day 1 and follow-up days)** |
| LABORATORY RESULTS[[33]](#footnote-33) |
| **HEMATOLOGY LBCAT=HEMATOLOGY SPEC TYPE = BLOOD** |
| **Were haematology samples** **taken**  **LBPERF LBSTAT** | **€** Yes **€** No  | **Date of sample collection** | **Time of sample collection** |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]** **LBDAT LBDTC**  | |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM**] **LBTIM LBDTC**  |
| **Haematology test name****LBTEST** | **Results****LBORRES** | **Units[[34]](#footnote-34)****LBORRESU** | **Was the result interpreted as clinically significant[[35]](#footnote-35) LBCLSIG** | **Test done****LBPERF LBSTAT** | **If no, provide reason****LBREASND** |
| Hemoglobin | **|\_\_|\_\_|.|\_\_| HGB\_LBORRES** | Hb (g/dL) **HGB\_LBORRESU** | **€** Yes | **€** No  | **€** Yes | **€** No  |  |
| Hemoglobin A1C | **|\_\_|\_\_|.|\_\_| HBA1C\_LBORRES** | Hba1c (mmol/mol) **HBA1C\_LBORRESU** | **€** Yes | **€** No  | **€** Yes | **€** No  |  |
| White cell count | **|\_\_|\_\_|\_\_|.|\_\_|WBC\_LBORRES** | WBC (109/L)**WBC\_LBORRESU** | **€** Yes | **€** No  | **€** Yes | **€** No |  |
| Red cell count | **|\_\_|\_\_|\_\_|.|\_\_|RBC\_LBORRES** | RBC (109/L)**RBC\_LBORRESU** | **€** Yes | **€** No  | **€** Yes | **€** No |  |
| Neutrophils | **|\_\_|\_\_|.|\_\_| NEUT\_LBORRES** | Neutrophils (109/L)**NEUT\_LBORRESU** | **€** Yes | **€** No  | **€** Yes | **€** No |  |
| Basophils | **|\_\_|\_\_|.|\_\_| BASO\_LBORRES** | Basophils (109/L)**BASO\_LBORRESU** | **€** Yes | **€** No  | **€** Yes | **€** No |  |
| Lymphocytes | **|\_\_|\_\_|.|\_\_| LYM\_LBORRES** | Lymphocytes (109/L)**LYM\_LBORRESU** | **€** Yes | **€** No  | **€** Yes  | **€** No |  |
| Monocytes | **|\_\_|\_\_|.|\_\_| MONO\_LBORRES** | Monocytes (109/L)**MONO\_LBORRESU** | **€** Yes | **€** No  | **€** Yes  | **€** No  |  |
| Eosinophils | **|\_\_|\_\_|.|\_\_| EOS\_LBORRES** | Eosinophils (109/L)**EOS\_LBORRESU** | **€** Yes | **€** No  | **€** Yes  | **€** No  |  |
| Platelets | **|\_\_|\_\_|\_\_|\_\_|****PLAT\_LBORRES** | Platelets (109/L)**PLAT\_LBORRESU** | **€** Yes | **€** No  | **€** Yes  | **€** No  |  |
| Prothrombin time | **|\_\_||\_\_| PT\_LBORRES** | Prothrombin time (seconds)**PT\_LBORRESU** | **€** Yes | **€** No  | **€** Yes  | **€** No  |  |
| International-normalised-ratio (INR) | **|\_\_|.|\_\_| INR\_LBORRES** |  | **€** Yes | **€** No  | **€** Yes  | **€** No  |  |
| D-Dimer | **|\_\_|.|\_\_||\_\_| DDIMER\_LBORRES** | D-Dimer (mg/L)  **DDIMER\_LBORRESU** | **€** Yes | **€** No  | **€** Yes  | **€** No  |  |
| Sickle Cells | **SCKLCE\_LBORRES** |  | **€** Yes | **€** No  | **€** Yes  | **€** No  |  |

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| **BIOCHEMISTRY[[36]](#footnote-36) LBCAT=BIOCHEMISTRY**  |
| **Were biochemistry samples taken? LBPERF LBSTAT** |  **€** Yes | **€** No | **Date of sample collection**  | **Time of sample collection**  |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]** **LBDAT LBDTC**  | |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** **LBTIM LBDTC**  |
| **Biochemistry test name****LBTEST** | **Results****LBORRES** | **Units[[37]](#footnote-37)****LBORRESU** | **Was the result interpreted as clinically significant[[38]](#footnote-38) LBCLSIG** | **Test done LBPERF LBSTAT** | **If no, provide reason****LBREASND** |
| AST | **|\_\_|\_\_|\_\_|\_\_|****AST\_LBORRES** | AST (IU/L)**AST\_LBORRESU** | **€** Yes  | **€** No | **€** Yes  | **€** No |  |
| ALT | **|\_\_|\_\_|\_\_|\_\_|****ALT\_LBORRES** | ALT (IU/L)**ALT\_LBORRESU** | **€** Yes  | **€** No | **€** Yes  | **€** No |  |
| Total Bilirubin | **|\_\_|\_\_|\_\_|.|\_\_|****BILI\_LBORRES** | Total bilirubin (µmol/L ) **BILI\_LBORRESU** | **€** Yes  | **€** No | **€** Yes  | **€** No |  |
| Direct Bilirubin | **|\_\_|\_\_|\_\_|.|\_\_|****BLDIR\_LBORRES** | Direct bilirubin ( µmol/L ) **BILDIR\_LBORRESU** | **€** Yes  | **€** No | **€** Yes  | **€** No |  |
| Creatinine | **|\_\_|\_\_|\_\_|\_\_|** **CREAT\_LBORRES** | Creatinine (µmol/L) **CREAT\_LBORRESU** | **€** Yes  | **€** No | **€** Yes  | **€** No |  |
| Albumin | **|\_\_|\_\_|\_\_|** **ALB\_LBORRES** | Albumin (g/L) **ALB\_LBORRESU** | **€** Yes  | **€** No | **€** Yes  | **€** No |  |
| Amylase | **|\_\_|\_\_|.|\_\_| AMYLASE\_LBORRES** | Amylase (U/L)**AMYLASE\_LBORRESU** | **€** Yes | **€** No  | **€** Yes  | **€** No  |  |
| Blood Urea | **|\_\_|\_\_|\_\_|** **UREAN\_LBORRES** | Urea Nitrogen (g/L) **UREAN\_LBORRESU** | **€** Yes  | **€** No | **€** Yes  | **€** No |  |
| Serum Potassium | **|\_\_|\_\_|\_\_|** **K\_LBORRES** | Potassium (mmol/L) **K\_LBORRESU** | **€** Yes  | **€** No | **€** Yes  | **€** No |  |
| Serum Sodium | **|\_\_|\_\_|.|\_\_| SODIUM\_LBORRES** | Sodium (mmol/L)**SODIUM\_LBORRESU** | **€** Yes | **€** No  | **€** Yes  | **€** No  |  |
| Creatinine Phosphokinase | **|\_\_|\_\_|.|\_\_| CK\_LBORRES** | Creatinine Kinase (U/L) **CK\_LBORRESU** | **€** Yes | **€** No  | **€** Yes  | **€** No  |  |
| Fasting Blood Glucose**LBTEST = Blood glucose and LBFAST = Y** | **|\_\_|\_\_|\_\_|** **GLU\_LBORRES** | Glucose (mmol/L) **GLU\_LBORRESU** | **€** Yes  | **€** No | **€** Yes  | **€** No |  |

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| **URINALYSIS LBCAT=URINALYSIS SPEC TYPE = URINE** |
| **Was a sample taken for urinalysis? LBPERF [[39]](#footnote-39) LBSTAT** | **€** Yes **€** No  | **Date and time of sample collection** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY] LBDAT LBDTC** |
| |\_\_|\_\_|:|\_\_|\_\_**|** **[HH:MM]** **LBTIM LBDTC** |
| **Urinalysis test name****LBTEST** | **Method****LBMETHOD** | **Results****LBORRES** | **If abnormal, clinically relevant LBCLSIG** |
| Blood | **€** Dipstix | **€** Negative  | € 1+  | € 2+  | € 3+ | € 4+  | **€** Yes  | **€** No |
| Protein | **€** Dipstix | **€** Negative  | € 1+  | € 2+  | € 3+ | € 4+  | **€** Yes  | **€** No |
| Glucose | **€** Dipstix | **€** Negative  | € 1+  | € 2+  | € 3+ | € 4+  | **€** Yes  | **€** No |
| Bilirubinuria | **€** Dipstix | **€** Negative  | € 1+  | € 2+  | € 3+ | € 4+  | **€** Yes  | **€** No |
| pH | **€** Dipstix | **|\_\_|.|\_\_| PH\_LBORRES** | **€** Yes  | **€** No |

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| PREGNANCY TESTING[[40]](#footnote-40) **LBCAT=PREGNANCY *Only applicable to women of child-bearing potential*** |
| **Was a sample taken for pregnancy testing?** **LBPERF LBSTAT** | **€** Yes  | **€** No  | **€** NA | **Date of sample collection** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY] LBDAT LBDTC** |
| **Pregnancy test name****LBTEST** | **Not done****LBPERF LBSTAT** | **Reason not done****LBREASND** | **Result LBORRES** |
|  | **€** | € Pre-menarche€ Permanently sterile[[41]](#footnote-41)€ Postmenopausal€ Refused test€ Other, specify below | € Negative | € Positive |

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| MICROBIOLOGY RESULTS MB |
| **Were samples taken for diagnostic tests? MBPERF MBSTAT**  |  **€** Yes | **€** No | **Date of sample collection**  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]** **MBDAT MBDTC** | **Time of sample collection** | |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** **MBTIM MBDTC** |
| **Diagnostic test name MBTEST** | **Results****MBORRES** | **Units[[42]](#footnote-42)****MBORRESU** | **If other, please specify**  | **Specimen Type MBSPEC** |  **Test done MBPERF MBSTAT** | **If no, provide reason****MBREASND** |
| Acid-Fast Bacilli | **€** Positive **€** Negative **AFB\_MBORRES** |  |  | **€** BLOOD**€** CEREBROSPINAL FLUID**€** SPUTUM**€** STOOL**€** URINE | **€** Yes  | **€** No |  |
| Cryptococcus Antigen | **|\_\_|\_\_||\_\_||\_\_|CRYPTCAG\_MBORRES** | **€** titer | **€** BLOOD**€** CEREBROSPINAL FLUID**€** SPUTUM**€** STOOL**€** URINE | **€** Yes  | **€** No |   |
| Toxoplasma gondii IgG Antibody | **|\_\_|\_\_||\_\_||\_\_|TGNIGGAB\_MBORRES** | **€** IU/mL | **€** BLOOD**€** CEREBROSPINAL FLUID**€** SPUTUM**€** STOOL**€** URINE | **€** Yes  | **€** No |  |
| Toxoplasma gondii IgM Antibody | **|\_\_|\_\_||\_\_||\_\_|TGNIGMAB\_MBORRES** | **€** IU/mL | **€** BLOOD**€** CEREBROSPINAL FLUID**€** SPUTUM**€** STOOL**€** URINE | **€** Yes  | **€** No |  |
| Toxoplasma gondii IgG/IgM Antibody | **|\_\_|\_\_||\_\_||\_\_|TGOGMAB\_MBORRES** |  | **€** BLOOD**€** CEREBROSPINAL FLUID**€** SPUTUM**€** STOOL**€** URINE | **€** Yes  | **€** No |  |
| Microorganism | **€** Pneumocystis Carinii **MCORGIDN\_MBORRES** | € Other**MCORGIDN\_MBORRES**  | Other, specify:**MBTESTOTH** | **€** BLOOD**€** CEREBROSPINAL FLUID**€** SPUTUM**€** STOOL**€** URINE | **€** Yes  | **€** No |  |

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| HIV DIAGNOSTIC TEST MB |
| **Was a HIV RDT[[43]](#footnote-43) performed?** **MBPERF MBSTAT**  | **€** Yes | **€** No | **If not done, give reason MBREASND**  |  | **If yes, date test performed****MBDAT MBDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |
| **Test type[[44]](#footnote-44)****MBTEST MBTESTCD** | **€**  HIV1AB **€**  HIV1AG | **€** Other | Other, specify **MBTESTOTH**  |  | **Result MBORRES\_QUAL** | **€** Positive  | **€** Negative  |
| **Was a Western Blot performed?** **MBPERF MBSTAT**  | **€** Yes | **€** No | **If not done, give reason MBREASND**  |  | **If yes, date test performed****MBDAT MBDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |
| **Test type[[45]](#footnote-45)****MBTEST MBTESTCD** | **€** HIV124AG **€** HIV12P24**€** HIV1AB24  | **€** Other | Other, specify **MBTESTOTH**  |  | **Result MBORRES\_QUAL** | **€** Positive  | **€** Negative |
| **CD4 count at baseline****LBTEST**  | **CD4\_LBORRES** | 10^6/L[[46]](#footnote-46) **CD4\_LBORRESU** | **Date CD4 sample taken LBDAT LBDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |
| **Viral load at baseline****MBTEST**  | **MBORRES\_QUAN** | copies/mL46 **MBORRESU** | **Date viral load sample taken MBDAT MBDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |

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| VISCERAL LEISHMANIASIS DIAGNOSTIC TEST MB |
| **Was a VL diagnostic test performed?** **MBPERF MBSTAT**  | **€** Yes | **€** No | **If not done, give reason MBREASND**  |  | **If yes, date test performed****MBDAT MBDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |
| **Test type****MBTEST MBTESTCD** | **€** rK39 RDT**[[47]](#footnote-47)**  **€** DAT**[[48]](#footnote-48)****€** IFAT**[[49]](#footnote-49)** **€** ELISA**[[50]](#footnote-50)** **€** Western Blot**€** Culture **€** Microscopy**€** Other  | Other, specify **MBTESTOTH**  |  | **Result MBORRES** | **€** Positive **€** Negative**€** Intermediate**MBORRES\_QUAL** |
|  **Titre** **MBORRES\_QUAN** |  |

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| PARASITOLOGICAL EXAMINATION [**MB] where MBCAT= VISCERAL LEISHMANIASIS MICROSCOPY** |
| **Was parasitological examination performed? MBPERF MBSTAT**  |  **€** Yes **€** No | **If not done, reason not done MBREASND** |  |
| **Date sample collected****MBDAT MBDTC** | **Time sample collected****MBTIM MBDTC**  | **Site of Aspirate****MBLOC** | **Result of Aspirate MBORRES\_QUAL** | **Grading of parasite count[[51]](#footnote-51) MBORRES\_QUAN** | **Units of grading MBORRESU\_QUAN** |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** | |\_\_|\_\_|:|\_\_|\_\_|**[HH:MM]**  | **€** Spleen **€** Bone marrow**€** Lymph Node  | **€** Positive | **€** 6+  | **€** 5+ | **€** 4+ | 10× eyepiece and 100× oil- immersion lens. Grading defines number of fields to be examined. |
| **€** 3+ | **€** 2+  | **€** 1+  |
| **€** Negative | **€** 0  |

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| **Was a sample taken for PCR, qPCR or LAMP? MBYN**[[52]](#footnote-52) | **€ Yes**  | **€ No** |
| **Date of sample collection** **MBDAT MBDTC** | **Test type****MBTEST****MBTESTCD** | **Sample type MBSPEC** | **Manufacturer****DIVAL when DIPARM=Manufacturer** | **Lot number****DIVAL when DIPARM=Lot** | **Trade name****DIVAL when DIPARM=Trade Name** | **Primers used MBMETHOD** |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** | **€** PCR **€** qPCR**€** LAMP | **€** Venous blood**€** Other (describe below)**MBSPREOTH** | **€** Eiken Chemical Co., Japan**€** Other (describe below)**DIVALOTH** |  |  | **€** ITS-1 **€** Other (describe below) **MBMETHODOTH** |
|  |  |  |
| **Not done****MBPERF MBSTAT** | **Reason not done MBREASND** | **Results qualitative MBORRES\_QUAL** | **Results quanitative MBORRES\_QUAN** | **Units of measure****MBORRESU\_QUAN** |
| **€**  |  | **€** Positive  | **€** Negative |  | **€** Parasites/uL of blood**€** Parasites/ug of genomic DNA |

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| TUBERCULOSIS EXAMINATION  |
| Microbiology Results **[MB]** |
| **Was a TB test performed?** **MBPERF MBSTAT** | **€** Yes **€** No | **If not done, give reason MBREASND**  |  |
| **Date sample collected MBDAT MBDTC** | **Time sample collected MBTIM MBDTC** | **Specimen type****MBSPEC**  | **Test Type**[[53]](#footnote-53)**MBTEST MBTESTCD** | **Method MBMETHOD** | **Results qualitative MBORRES\_QUAL** | **Grading of sputum smear****MBORRES** |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |  |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | **€** LAVAGE FLUID**€** SPUTUM**€** BLOOD**€** URINE**€** STOOL | **€** AFB**€** MTB**€** MTBCMPLX **€** LAM**€** IFNG**€** Other | **€** ACID FAST STAIN**€** AURAMINE STAIN**€** ZIEHL NEELSEN ACID FAST STAIN**€** NUCLEIC ACID AMPLIFICATION TEST**€** POLYMERASE CHAIN REACTION**€** MICRO-LATEX PARTICLE-MEDIATED IMMUNOASSAY**€** MICROBIAL CULTURE**€** ELISPOT**€** ELISA**€** DIPSTICK MEASUREMENT METHOD | **€** Positive | **€** 6+ **€** 5+  **€** 4+ **€** 3+ **€** 2+ **€** 1+ |
| **Other, specify****MBTESTOTH** | **€** Negative | **€** 0 |
|  | **Results quanitative MBORRES\_QUAN** | **Units of measure MBORRESU\_QUAN** |
| |\_\_|\_\_|\_\_|\_\_|\_\_||\_\_|\_\_|.|\_\_| | **€** CFU **€** CFU/mL **€** IU/mL **€** SFC/10^6 PBMC |
| Radiology Findings [RE] |
| **Pre-specified result targeted by test**[[54]](#footnote-54)**RERESTRG** | **Date of radiograph REDAT REDTC** | **Location of radiograph****RELOC**  | **Result REORRES**  | **Not done REPERF RESTAT** | **Reason not done REREASND** |
| **€** Volume Loss**€** Volume Collapse**€** Cavitation**€** Infiltrates**€** Granulomas**€** Miliary Tuberculosis**€** Apical Cap**€** Pleural Effusion**€** Pleural Thickening**€** Costophrenic Angle Obliteration**€** Tracheal Deviation**€** Adenopathy**€** Calcification**€** Cardiomegaly**€** Pericardial Enlargement | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** | **€** LUNG**€** LYMPH NODE HILUM**€** LYMPH NODE MEDIASTINUM | **€** PRESENT**€** ABSENT | **€** |  |
| Ultrasound Findings [MO] |
| **Pre-specified result targeted by test**[[55]](#footnote-55)**MORESTRG** | **Date of ultrasound MODAT MODTC** | **Location of ultrasound****MOLOC** | **Result MOORRES** | **Not done MOPERF MOSTAT** | **Reason not done MOREASND** |
| **€** Pericardial Effusion**€** Abdominal Lymph nodes**€** Unilateral Pleural Effusion**€** Bilateral Pleural Effusion**€** Focal Liver Lesions**€** Ascites in the Pouch of Morison**€** Focal Spleen Lesions**€** Ascites in spleno-renal pouch**€** Ascites in the Pouch of Douglas**€** Pulmonary SUNs**€** Pulmonary Consolidations | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** | **€** EPIGASTRIC REGION**€** ABDOMINAL CAVITY**€** SUPRAPUBIC REGION**€** THORAX | **€** PRESENT**€** ABSENT**€** FEW**€** MANY | **€** |  |

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| CONCOMITANT DISEASE DIAGNOSTIC TEST MB |
| **Was a test for Giardia detection performed? MBPERF MBSTAT**  | **€** Yes | **€** No | **If not done, give reason MBREASND** |  | **If yes, date test performed****MBDAT MBDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |
| **Was a test for Entamoeba detection performed? MBPERF MBSTAT** | **€** Yes | **€** No | **If not done, give reason MBREASND** |  | **If yes, date test performed****MBDAT MBDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |
| **Was a test for Ancylostomatoidea detection performed? MBPERF MBSTAT** | **€** Yes | **€** No | **If not done, give reason MBREASND** |  | **If yes, date test performed****MBDAT MBDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |
| **Was a test for Cestoda detection performed? MBPERF MBSTAT** | **€** Yes | **€** No | **If not done, give reason MBREASND** |  | **If yes, date test performed****MBDAT MBDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |
| **Was a test for Strongyloides detection performed? MBPERF MBSTAT** | **€** Yes | **€** No | **If not done, give reason MBREASND** |  | **If yes, date test performed****MBDAT MBDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |
| **Was a test for Acaris Lumbricoides detection performed? MBPERF MBSTAT** | **€** Yes | **€** No | **If not done, give reason MBREASND** |  | **If yes, date test performed****MBDAT MBDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |
| **Was a test for Wuchereria detection performed? MBPERF MBSTAT** | **€** Yes | **€** No | **If not done, give reason MBREASND** |  | **If yes, date test performed****MBDAT MBDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |
| **Was a malaria RDT performed?** **MBPERF MBSTAT** | **€** Yes | **€** No | **If not done, give reason MBREASND**  |  | **If yes, date test performed****MBDAT MBDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |
| **Test type****MBTEST MBTESTCD** | **€** PLHDAG**€** HRP2AG**€** LDHRP2AG  | **€** Other | **Other, specify** **MBTESTOTH**  |  | **Result MBORRES** | **€** Positive **€** Negative**€** Not tested**MBORRES\_QUAL** |
| **Was a Hepatitis C test performed?** **MBPERF MBSTAT** | **€** Yes | **€** No | **If not done, give reason MBREASND**  |  | **If yes, date test performed****MBDAT MBDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |
| **Test type****MBTEST MBTESTCD** | **€** PCR **€** HCAB  | **€** Other | Other, specify **MBTESTOTH**  |  | **Result MBORRES** | **€** Positive **€** Negative**€** Not tested**MBORRES\_QUAL** |
| **Was a Hepatitis B test performed?** **MBPERF MBSTAT** | **€** Yes | **€** No | **If not done, give reason MBREASND**  |  | **If yes, date test performed MBDAT MBDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |
| **Test type****MBTEST MBTESTCD** | **€** HBAG **€** HBAB  | **€** Other | Other, specify **MBTEST**  |  | **Result MBORRES** | **€** Positive **€** Negative**€** Not tested**MBORRES\_QUAL** |

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| **MALARIA MICROSCOPY MBCAT = MALARIA MICROSCOPY****REPEAT AS PER PROTOCOL** |
| **Collection date and time****MBDAT MBDTC** **MBTIM MBDTC** | **Reader number[[56]](#footnote-56)****MBEVAL** | **Slide quality****MBSPCCND** | **Smear type****MBMETHOD** | **Parasite type[[57]](#footnote-57) [[58]](#footnote-58)****MBTEST MBTESTCD** | **Parasite count[[59]](#footnote-59) MBORRES**  | **Parasite count units[[60]](#footnote-60)****MBORRESU** | **Malaria species[[61]](#footnote-61)****MBTEST MBTESTCD** |
| **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** **[DD-MMM-YYYY]****|\_\_|\_\_|:|\_\_|\_\_|** **[HH:MM]** |  | **€** Good **€** Poor**€** Missing | **€** Thick smear **€** Thin smear | **€** Asexual**€** Sexual | **|\_\_|\_\_|\_\_|\_\_|** | **€** /\_\_\_\_\_WBC | **€** /\_\_\_\_\_HPF | **€** /\_\_\_\_\_RBC | **€**Pf **€**Pv **€**Po**€**Pm **€**Pk |
| **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** **[DD-MMM-YYYY]****|\_\_|\_\_|:|\_\_|\_\_|** **[HH:MM]** |  | **€** Good **€** Poor**€** Missing | **€** Thick smear **€** Thin smear | **€** Asexual**€** Sexual | **|\_\_|\_\_|\_\_|\_\_|** | **€** /\_\_\_\_\_WBC | **€** /\_\_\_\_\_HPF | **€** /\_\_\_\_\_RBC | **€**Pf **€**Pv **€**Po**€**Pm **€**Pk |
| **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** **[DD-MMM-YYYY]****|\_\_|\_\_|:|\_\_|\_\_|** **[HH:MM]** |  | **€** Good **€** Poor**€** Missing | **€** Thick smear **€** Thin smear | **€** Asexual**€** Sexual | **|\_\_|\_\_|\_\_|\_\_|** | **€** /\_\_\_\_\_WBC | **€** /\_\_\_\_\_HPF | **€** /\_\_\_\_\_RBC | **€**Pf **€**Pv **€**Po**€**Pm **€**Pk |
| **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** **[DD-MMM-YYYY]****|\_\_|\_\_|:|\_\_|\_\_|** **[HH:MM]** |  | **€** Good **€** Poor**€** Missing | **€** Thick smear **€** Thin smear | **€** Asexual**€** Sexual | **|\_\_|\_\_|\_\_|\_\_|** | **€** /\_\_\_\_\_WBC | **€** /\_\_\_\_\_HPF | **€** /\_\_\_\_\_RBC | **€**Pf **€**Pv **€**Po**€**Pm **€**Pk |

*Once all investigations have been completed the eligibility criteria page will be completed; if the participant is eligible for the study as detailed in the study protocol, the randomisation module will be completed, and treatment phase will be started.*

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| **TREATMENT PHASE (DAY1)** |
| STUDY DRUG ADMINISTRATION[[62]](#footnote-62) [[63]](#footnote-63) [**EC]** |

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| **DRUG SENSITIVITY TESTING** *Complete if patient receives Amphotericin B IV* |
| **Was drug sensitivity testing done? ECYN** | **€** Yes  | **€** No  | **If yes, dose given ECDSTXT ECDOSTXT/ECDOSE** |  | **Units ECDOSU** | **€** Mg  | **Result AETERM where AECAT = TEST DOSE** | **€** Reaction |
| **€** No reaction |

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| *Please complete a separate CRF page for each study drug administered* |
| **ORAL MEDICATION** |
| **Was oral medication given** **ECYN****ECROUTE = ORAL** | **If yes name of drug ECTRT** | **Prescribed daily amount ECDSTXT ECDOSTXT/ECDOSE** | **Dose units****ECDOSU** | **Weight used to calculate dose at Day 1****VSORRES VSORRESU = “kg”** | **Frequency of dose administration[[64]](#footnote-64) ECDOSFRQ** |
| **€** Yes  | **€** No  |  |  | **€** mg/day | |\_\_|\_\_|.|\_\_|kg | **€** QD | **€** BID | **€** TID | **€** QID |
| **EXAMPLE OF AN ORAL DOSE SCHEDULE GIVEN TWICE DAILY** |
| **Date dose administered****ECSTDAT ECSTDTC****Time dose administered****ECSTTIM ECSTDTC** | **OR****Missed dose ECPERF ECSTAT** | **Reason for missed dose****ECREASND** | **Dose formulation ECDOSFRM** | **Number of tablets/****capsules given** **ECDSTXT ECDOSTXT/ECDOSE** | **Dose amount/capsule or tablet (mg) ECDOSE** | **Did the subject vomit within (xx) minutes of the dose FAORRES where FAOBJ = VOMITING, FACAT = POST-DOSE VOMITING; When vomiting occurs, an AE record is created where AEPRESP=Y and AETERM=VOMITING AEOCCUR** | **Time of vomit****AESTTIM****AESTDTC** | **Dose/Re-treatment****RDIND****SUPPEC.QVAL** |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]**|\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | € |  | € Tablet€ Capsule |  | |\_\_||\_\_||\_\_| | € Yes  | € No  | |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | € Dose € Re-dose  |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]**|\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | € |  | € Tablet€ Capsule |  | |\_\_||\_\_||\_\_| | € Yes  | € No  | |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | € Dose € Re-dose  |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]**|\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | € |  | € Tablet€ Capsule |  | |\_\_||\_\_||\_\_| | € Yes  | € No  | |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | € Dose € Re-dose  |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]**|\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | € |  | € Tablet€ Capsule |  | |\_\_||\_\_||\_\_| | € Yes  | € No  | |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | € Dose € Re-dose  |

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| **INTRAVENOUS/INTRAMUSCULAR INJECTION** |
| *Please complete a separate CRF page for each study drug administered* |
| **Was intravenous or intramuscular treatment given. If, yes ECDOSFRM=INJECTION** | **If yes, give name of drug ECTRT** | **Dose units****ECDOSU** | **Weight used to calculate dose at Day 1[[65]](#footnote-65) VSORRES VSORRESU = “kg”** | **Frequency of dose administration[[66]](#footnote-66) ECDOSFRQ** | **Route of administration[[67]](#footnote-67) ECDOSROUTE** |
| **€** Yes  | **€** No  |  | € mg | € mg/kg | |\_\_|\_\_|.|\_\_|kg | **€** QD  | **€** BID | **€** IV | **€** IM |
| **EXAMPLE OF AN INTRAVENOUS/MUSCULAR DOSE SCHEDULE GIVEN DAILY** |
| **Date of dose ECSTDAT ECSTDTC****Time of dose ECSTTIM ECSTDTC** | **Dose amount prescribed ECDOSRGM** | **Dose amount given ECDSTXT ECDOSTXT/ECDOSE** | **Was study treatment interrupted[[68]](#footnote-68) AETERM, AEAACN** | **If yes, give reason ECADJ** | **Was treatment permanently discontinued If “Yes” create DSDECOD** | **If treatment permanently discontinues, give reason DSDECOD/DSTERM** | **If other, specify DSDECOD/DSTERM** |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]**|\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | **|\_\_||\_\_||\_\_||\_\_|** | **|\_\_||\_\_||\_\_||\_\_|** | **€** Changed **€** Interrupted |  | **€** Yes **€** No  | **€** Adverse event **€** Other  |  |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]**|\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | **|\_\_||\_\_||\_\_||\_\_|** | **|\_\_||\_\_||\_\_||\_\_|** | **€** Changed **€** Interrupted  |  | **€** Yes **€** No  | **€** Adverse event **€** Other  |  |

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| **FOLLOW-UP ASSESSMENTS VISIT DAY2 etc** |
| **Was the visit completed? VISYN** | **€** Yes | **€** No |
| **Date of visit VISDAT VISDTC** | **OR reason not completed** DSTERM |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** | **€** Withdrew consent**€** Withdrawn due to adverse event**€** Withdrawn due to treatment failure**€** Lost to follow-up**€** Death**€** Other, specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

*Repeat data modules/case report forms relevant to protocol EG. Signs & symptoms of HIV/VL, physical examination, laboratory tests, pregnancy test, ECG, audiometry, and/or parasitological tests.*

*Note: Adverse event monitoring and concomitant medication completion need to be completed at each visit.*

*NB: Most studies will report on initial treatment and clinical outcome at Day28 0r Day30, at this visit the following modules needs to be completed in addition to the modules repeated above:*

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| HIV ASSESSMENT**[[69]](#footnote-69)** |
| **If the patient was on ART at baseline, has it been changed? ECDOSADJ** | **€** Yes | **€** No |
| **If yes, reason for switch ECADJ** | **€** Adverse Events  **€** ART failure **€** Other | **Other, specify** |  |
| **If the patient was not on ART at baseline, has it been initiated? ECYN** | **€** Yes | **€** Yes (for patient requiring ATT) | **€** No |
| **Referral ART centre name HOSPID** |  | **ART start date****ECSTDAT ECSTDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |
| **ART number ECSPID** |  | **Current ART regimen ECDOSRGM** |  |
| **Number of days ART doses were missed in last month**  | **€** None | **€** 1-7 | **€** 8-14 | **€** >14 | **€** UNK[[70]](#footnote-70) |
| **Remark on adherence COVAL CO.COVAL** |  |

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| TUBERCULOSIS ASSESSMENT |
| **If the patient was diagnosed with TB at baseline, has ATT been initiated? ECYN** | **€** Yes | **€** No |
| **Referral ATT centre name (if applicable) HOSPID** |  |
| **Regimen used**[[71]](#footnote-71)**: ECTRT** | **€** INH **€** RIF **€** PZA  **€** EMB **€** SM **€** Other  | Other, specify: |
| **National TB programme registration number ECSPID** |  | **ATT start date****ECSTDAT ECSTDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |
| **Number of days ATT doses were missed in last month**  | **€** None | **€** 1-7 | **€** 8-14 | **€** >14 | **€** UNK[[72]](#footnote-72) |
| **Remark on adherence COVAL CO.COVAL** |  |
| **Was co-trimoxazole given? ECOCCUR, ERPRESP=”Y”** | **€** Yes **€** No | **If yes, why was treatment regimen changed? ECADJ** |  |

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| POST-KALA-AZAR DERMAL LEISHMANIASIS (PKDL) ASSESSMENT |
| **Does the patient have signs /symptoms of dermal leishmaniasis at this visit[[73]](#footnote-73)? PEORRES where PETEST = POST KALA-AZAR DERMAL LEISHMANIASIS** | **€** Yes | **€** No |
| **If the patient did not have PKDL at baseline, has it developed? AEYN** | **€** Yes | **€** No | **€** NA**[[74]](#footnote-74)** |
| **If the patient had PKDL at baseline, has it worsened[[75]](#footnote-75)? AEYN** | **€** Yes | **€** No | **€** NA |
| **If yes for either PKDL questions, give date PKDL developed (if not present at baseline), OR date PKDL worsened (present at baseline) ECSTDAT ECSTDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |
| **If the patient had/developed PKDL, was it treated?****ECYN** | **€** Yes | **€** No | **€** NA |
| **If yes, what treatment was given and when ECTRT** |  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]**  **ECSTDAT ECSTDAT** |
| *The grading of PKDL is currently being completed for the Africa regions where VL is endemic (such as Sudan), refer to the VL data standard user guide for more information* |
| **If relevant, severity of PKDL[[76]](#footnote-76)**  **PESEV** | **€** Mild[[77]](#footnote-77) | **€** Moderate[[78]](#footnote-78) | **€** Severe[[79]](#footnote-79) |
| **Type of skin lesions PEORRES** | **€** Macular | **€** Papular | **€** Nodular | **€** Mucosal | **€** Mixed |

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| FEVER CLEARANCE **VS**  | VISIT DAY 28 |
| *Fever clearance time will be calculated from date and time of onset of treatment to date and time of the last fever peak, after which there was a period of at least 72 hours with no fever. Record below the details of the last fever peak after which there was a period of at least 72 hours with no fever, or as specified in the protocol* |
| **Date temperature measured VSDAT VSDTC** | **Time temperature measured VSTIM VSDTC** | **Temperature TEMP\_VSORRES** | **Units of measure VSORRESU** | **Method of measurement VSMETHOD** |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]** | |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]**  | |\_\_|\_\_|.|\_\_| | **€** °C **€** °F | **€** Oral**€** Tympanic |

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| RESCUE MEDICATION (documentation of any additional or alternative anti-leishmanial drugs during the study period)[[80]](#footnote-80) **CMCAT=rescue** |
| **Was rescue medication given? CMYN** | **Reason for initiation of rescue treatment**  **CMINDC** | **If other, specify** **CMINDC** |
| **€** Yes  | **€** No | **€** Adverse event  | **€** Initial failure (DXX) | **€** Relapse | **€** PKDL  | **€** Other |  |
| **Medication name CMTRT** | **Frequency[[81]](#footnote-81)****CMDOSFRQ** | **Dose formulation****CMDOSFRM** | **Dose amount****CMDOSE** | **Units CMDOSU** | **Route of administration[[82]](#footnote-82) CMROUTE** | **Start date CMSTDAT CMSTDTC****Start time CMTIM CMSTDTC** | **End date CMENDAT CMENDTC****End time CMENTIM CMENDTC** |
|  | **€** QD**€** BID**€** TID**€** QID | **€** tablet**€** capsule**€** susp.**€** injection |  | **€** mL**€** mg | **€** PO**€** IM**€** IV | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |
| |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** |
|  | **Ongoing? CMONGO CMENRTPT/CMENRF** | **€**  |
|  | **€** QD**€** BID**€** TID**€** QID | **€** tablet**€** capsule**€** susp.**€** injection |  | **€** mL**€** mg | **€** PO**€** IM**€** IV | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |
| |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** |
|  | **Ongoing? CMONGO CMENRTPT/CMENRF** | **€**  |
|  | **€** QD**€** BID**€** TID**€** QID | **€** tablet**€** capsule**€** susp.**€** injection |  | **€** mL**€** mg | **€** PO**€** IM**€** IV | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |
| |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** |
|  | **Ongoing? CMONGO CMENRTPT/CMENRF** | **€**  |
|  | **€** QD**€** BID**€** TID**€** QID | **€** tablet**€** capsule**€** susp.**€** injection |  | **€** mL**€** mg | **€** PO**€** IM**€** IV | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |
| |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** |
|  | **Ongoing? CMONGO CMENRTPT/CMENRF** | **€**  |
| *If yes, complete details here rather than on the concomitant medications page (there shouldn’t be duplication of data)* |

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| ADVERSE EVENTS **[AE]** *(make multiple copies of this page if necessary)* |
| **Any AEs? AEYN [[83]](#footnote-83)** | **€** Yes | **€** No | **What is the AE term? AETERM** |  | **AE number AESPID** |  |
| **Start date/time** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY]****AESTDAT AESTDTC** | **End date/time** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|****[DD-MMM-YYYY] AEENDAT AEENDTC** | **Ongoing? AEONGO** **AEENRTPT/AEENRF** |
| **|\_\_|\_\_|:|\_\_|\_\_| [HH:MM]****AESTTIM AESTDTC** | **|\_\_|\_\_|:|\_\_|\_\_| [HH:MM]****AEENTIM AEENDTC** | **€** |
| **Standard toxicity grade[[84]](#footnote-84)****AETOXGR** | **€** Grade 1 | **€** Grade 2 | **€** Grade 3 | **€** Grade 4 | **€** Grade 5 |  |
| **Outcome****AEOUT** | **€** Recovered/Resolved | **€** Recovered/Resolved with sequelae | **€** Recovering/Resolving | **€** Not recovered/Not resolved | **€** Fatal | **€** Unknown |
| **Relationship to study treatment AEREL** | **€** Not related | **€** Probably not related | **€** Possibly related | **€** Probably related | **€** Definitely related |
| **Action taken with study treatment AEACN** | **€** Dose increased | **€** Dose reduced | **€** Dose not changed | **€** Drug interrupted | **€** Drug withdrawn | **€** Not applicable | **€** Unknown |
| **Is the AE serious[[85]](#footnote-85)****AESER** | **Is this a special interest AE? AESI** | **Was a concomitant or additional treatment given due to this adverse event? AECONTRT** | **Was the AE detected at a medically attended visit[[86]](#footnote-86)?** **MAAE** |
| **€** Yes | **€** No | **€** Yes | **€** No | **€** Yes | **€** No | **€** Yes | **€** No |
| **Give short description of the AE** |  |

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| SERIOUS ADVERSE EVENTS – REPEAT AS REQUIRED |
| **What is the AE number**  | **AE number AESPID** |  |
| **SAE Classification** | **€** Fatal[[87]](#footnote-87) **AESDTH****€** Life threatening **AESLIFE****€** Requires or prolongs hospitalization **AESHOSP****€** Results in permanent or significant disability/incapacity **AESDISAB****€** Congenital anomaly/birth defect **AESCONG****€** Medically significant **AESMIE**Describe medically significant condition: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **If hospitalization/ prolonged hospitalization give admission date****HOSTDAT where HOTERM = HOSPITALIZATION****HOSTDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |
| **If hospitalization/prolonged hospitalization give discharge date****HOENDAT where HOTERM = HOSPITALIZATION****HOENDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |
| **Give short description of the SAE** |  |

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| CONCOMITANT MEDICATION [[88]](#footnote-88) [**CM]** |
| **Did the patient receive a transfusion? CMYN**  | **€** Yes  | **€** No |
| **Blood Product CMTRT** | **Dose amount****CMDOSE?** | **Units CMDOSU**[[89]](#footnote-89) | **Start date CMSTDAT CMSTDTC****Start time CMTIM CMSTDTC** | **End date CMENDAT CMENDTC****End time CMENTIM CMENDTC** |
| **€** Whole Blood**€** Red Blood Cells**€** Plasma**€** Platelets**€** Cryoprecipitate |  | **€** mL**€** U**€** Pt\_br**€** Pt\_us | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |
| |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** |
| **Was any medication given? CMYN** [[90]](#footnote-90) | **€** Yes[[91]](#footnote-91)  | **€** No |
| **Medication name****CMTRT** | **Category of treatment****CMCAT** | **Frequency[[92]](#footnote-92)****CMDOSFREQ** | **Dose formulation****CMDOSFRM** | **Dose amount****CMDOSE** | **Units CMDOSU** | **Route of administration[[93]](#footnote-93)CMROUTE** | **Start date CMSTDAT CMSTDTC****Start time CMTIM CMSTDTC** | **End date CMENDAT CMENDTC****End time CMENTIM CMENDTC** | **Indication****CMINDC** |
|  | **€** Prior**€** During | **€** QD**€** BID**€** TID**€** QID | **€** tablet**€** susp.**€** injection |  | **€** mL**€** mg | **€** PO**€** TOP**€** SC**€** IM**€** IV**€** PR  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |  |
| |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** |
|  | **Ongoing? CMONGO CMENRTPT/CMENRF** | **€**  |
|  | **€** Prior**€** During | **€** QD**€** BID**€** TID**€** QID | **€** tablet**€** susp.**€** injection |  | **€** mL**€** mg | **€** PO**€** TOP**€** SC**€** IM**€** IV**€** PR  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |  |
| |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** |  |
|  | **Ongoing? CMONGO CMENRTPT/CMENRF** | **€**  |  |

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| INITIAL OUTCOME AT DAY 28**[[94]](#footnote-94)** [RS/DS**]** RSORRES/DSTERM |
| **€** Initial cure[[95]](#footnote-95) | Clinical improvement, defined as improvement of clinical signs and symptoms (absence of fever attributed to VL, reduction in spleen size and improvement of haematological parameters); absence of parasites in the spleen or bone marrow microscopy, and no rescue therapy on or before Day 28 |
| **€** Potential cure/Slow responder | Clinical improvement, defined as improvement of clinical signs and symptoms (absence of fever attributed to VL, reduction in spleen size and improvement of haematological parameters); but 1+ parasites in the spleen or bone marrow microscopy, and no rescue therapy on or before Day 28 |
| **€** Initial failure | Presence of >1+ parasites in spleen or bone marrow on microscopy, requiring rescue therapy on or before Day 28 |

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| SUBJECT DISPOSITION **[DS] DSCAT = DISPOSITION EVENT** |
| **Did the subject complete the study and all follow-up visits**[[96]](#footnote-96)**? DSTERM** | **€ Yes**  | **€ No** |
| **[DSDECOD]** | **€** Completed  |
| **If no, list reason for non-completion [DSDECOD]** | **€** Adverse event |
|  | **€** Disease relapse |
|  | **€** Initial failure |
|  | **€** Lost to follow-up |
|  | **€** Non-compliance with study drug |
|  | **€** Death |
|  | **€** Physician decision. Give reason: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | **€** Withdrawal by parent/guardian |
|  | **€** Withdrawal by subject |
|  | **€** Protocol major deviation |
| **What was the date of the final assessment**[[97]](#footnote-97) **DSSTDAT DSSTDTC** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY]** |

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| OVERALL RESPONSE TO TREATMENT [[98]](#footnote-98)**[RS] where RSTEST=OVERALL RESPONSE** |
| *This section will be completed for all patients in the trial at their last study visit, this might not be the final protocol defined study visit EG, Day 180 such as instances where a patient died or was considered lost-to-follow-up.* |
| **€** | **Final Cure –** absence of signs and symptoms of VL at last study visit (EG. Day 180), and no rescue treatment at any time during the study **RSORRES\_CURE** |
| **€** | **Failure – Initial Failure**: presence of parasites in spleen or bone marrow on microscopy, requiring rescue therapy at or before day 28 **RSORRES\_PARASITIOLOGICAL FAILURE** |
| **€** | **Failure – Relapse**: Initial cure at Day 28, but presented with clinical signs and symptoms of VL with confirmed presence of parasites in spleen or bone marrow on microscopy after day 28 **RSORRES\_RELAPSE** |
| **€** | **Failure** – Treatment discontinuation due to (S)AE related to the study drug, requiring rescue therapy **RSORRES\_TREATMENT\_DISCONTINUED** |
| **€** | **Failure -** Death associated with VL or related to the study drug **RSORRES\_DEATH** |
| **€** | **Other –** Non-completion due to withdrawal, death not related to VL, lost to follow up, protocol violation etc. **RSORRES\_TREATMENT\_DISCONTINUES** |
| Comment |  |

# APPENDICES

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| APPENDIX A |
| DETAILED PREGNANCY ASSESSMENT **[RP]** |
| **Is the subject pregnant?****RPTEST=Pregnant During the Study****RPTESTCD=PREGST** | **€** Yes | **€** No | **€** UNK[[99]](#footnote-99) | **€** NA[[100]](#footnote-100) | **If yes, date of last menstrual period (LMP) RPTEST= Last Menstrual Period Start Date****RPTESTCD=LMPSTDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |
| **RPORRES where RPTEST = Pregnant During the Study** |  |
| **If pregnant, estimate gestational age** **RPTEST=Estimated Gestational Age****RPTESTCD=EGESTAGE** | **|\_\_|\_\_|** **RPORRES where RPTEST=Estimated Gestational Age** | **Weeks RPORRESU where RPTEST=Estimated Gestational Age** |
| **Gestational age determined by****RPMETHOD where RPTESTCD=EGESTAGE** | **If other, specify****RPMETHOTH** |
| **€** Fundal ht[[101]](#footnote-101) | **€** LMP[[102]](#footnote-102)  | **€** Ultrasound | **€** Other |  |

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| APPENDIX B |
| AUDIOMETRIC EXAMINATION[[103]](#footnote-103) **[AU]** |  **Was Audiometry performed?****AUYN [[104]](#footnote-104)** | **€ Yes**  | **€ No**  | **€ NA[[105]](#footnote-105)** |
| **Date of Audiometry AUDAT AUDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |  |
| **THRESHOLD FREQUENCY[[106]](#footnote-106)** |
| **Frequency (Hz)****AUTEST AUTESTCD** | **Ear Side****AULAT** | **Results AUORRES** | **Units****[[107]](#footnote-107)****AUORRESU** | **Ear Side****AULAT** | **Results AUORRES** | **Units****AUORRESU** |
| **1000** | LEFT | **|\_\_|\_\_|****1000HL\_AUORRES** | dB | RIGHT | **|\_\_|\_\_|****1000HR\_AUORRES** | dB |
| **2000** | LEFT | **|\_\_|\_\_|****2000HL\_AUORRES** | dB | RIGHT | **|\_\_|\_\_|****2000HR\_AUORRES** | dB |
| **3000** | LEFT | **|\_\_|\_\_|****3000HL\_AUORRES** | dB | RIGHT | **|\_\_|\_\_|****3000HR\_AUORRES** | dB |
| **4000** | LEFT | **|\_\_|\_\_|****4000HL\_AUORRES** | dB | RIGHT | **|\_\_|\_\_|****4000HR\_AUORRES** | dB |
| **6000** | LEFT | **|\_\_|\_\_|****6000HL\_AUORRES** | dB | RIGHT | **|\_\_|\_\_|****6000HR\_AUORRES** | dB |
| **8000** | LEFT | **|\_\_|\_\_|****8000HL\_AUORRES** | dB | RIGHT | **|\_\_|\_\_|****8000HR\_AUORRES** | dB |
| **Otoscopic Findings[[108]](#footnote-108) AUINTP** | **Left ear AULAT** | **€** Normal  | **€** Abnormal | **Right ear AULAT** | **€** Normal  | **€** Abnormal |
| **If abnormal, describe AUORRES** |  |  |

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| APPENDIX C |
| PHARMACOKINETIC SAMPLING [[109]](#footnote-109)  [PK] | **Was PK sampling performed?****PCYN**[[110]](#footnote-110) | **€ Yes**  | **€ No** | **€ NA[[111]](#footnote-111)** |
| **Date and actual time of sample collection** **PCDAT PCDTC PCTIM PCDTC** | **Time-point[[112]](#footnote-112)****PCTPT** | **Sample type PCSPEC** | **Sample condition****PCSPCCND** | **Not done****PCPERF PCSTAT** | **Reason not done****PCREASND** |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]**|\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | **PREDOSE** | **€** Serum**€** Plasma |  | **€**  |  |
| **€** Blood  | **€** Dried |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]**|\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | **D1H6** | **€** Serum**€** Plasma |  | **€**  |  |
| **€** Blood | **€** Dried |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]**|\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | **D7** | **€** Serum**€** Plasma |  | **€**  |  |

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| APPENDIX D |
| RADIOLOGY SCREENING [RE] | **Was Radiology done for this study? REYN** | **€ Yes**  | **€ No** |
| **Radiology type[[113]](#footnote-113) REMETHOD** | **Date of radiograph REDAT REDTC** | **Location of radiograph RELOC** | **Result RECLSIG** | **Not done****REPERF RESTAT** | **Reason not done****REREASND** |
| **€** Radiograph **€** Ultra-sound**€** POCUS**[[114]](#footnote-114)**  **€** CT scan**€** Other | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** | € Chest € Spleen€ Liver € Other (describe below) **RELOCOTH** | € Normal € Abnormal NCS (describe below)€ Abnormal CS (describe below) **REORRES** | **€**  |  |
|  |  |
| **€** Radiograph **€** Ultra-sound**€** POCUS **€** CT scan**€** Other | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** | € Chest € Spleen€ Liver € Other (describe below) **RELOCOTH** | € Normal € Abnormal NCS (describe below)€ Abnormal CS (describe below) **REORRES** | **€**  |  |

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| APPENDIX E |
| G6PD **LBTEST = Glucose-6-Phosphate\_Dehydrogenase[[115]](#footnote-115)****LB** | **Was a sample for G6PD testing taken? LBPERF[[116]](#footnote-116)** | **€** Yes  | **€** No  | **€** NA[[117]](#footnote-117) |
| **Collection date LBDAT LBDTC****Collection time LBTIM LBDTC** | **Test category****LBMTHCAT** | **Test type****DIVAL where DIPARM=Device type** | **Trade name****DIVAL when DIPARM=Trade Name** | **Sample type****LBSPEC** | **Sample condition****LBSPCCND** | **Result****LBORRES** | **Units****LBORRESU** | **Not done****LBPERF LBSTAT** | **Reason not done****LBREASND** |
| **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** **[DD-MMM-YYYY]****|\_\_|\_\_|:|\_\_|\_\_|** **[HH:MM]** | **€** Qualitative | **€** Fluorescence spot test**€** RDT**€** Other |  | **€** Whole blood  | **€** Dried | **€** Normal**€** Deficient**€** Invalid |  | **€** |  |
| Other, specify: |
| **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|** **[DD-MMM-YYYY]****|\_\_|\_\_|:|\_\_|\_\_|** **[HH:MM]** | **€** Quantitative | **€** Spectrophotometry**€** Biosensor**€** WST 8/1 assay**€** Other  |  | **€** Whole blood  | **€** Dried | **|\_\_||\_\_|.|\_\_||\_\_|** | Per gram hemoglobin | **€** |  |
| Other, specify: |

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| APPENDIX F |
| OPHTHALMIC EXAMINATION **[OE]** |  **Was Ophthalmoscopy performed?****OEYN [[118]](#footnote-118)** | **€ Yes**  | **€ No**  | **€ NA[[119]](#footnote-119)** |
| **Date of Ophthalmoscopy OEDAT OEDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**[DD-MMM-YYYY]** |  |
| **Test type OETEST OETESTCD** | **€** Ophthalmic Examination | **Result[[120]](#footnote-120) OEORRES** | **­­­** | **Lens examined OELAT** | **€** Left | **€** Right |
| **Ophthalmic Findings OEINTP** | **Left eye OELAT** | **€** Normal | **€** Abnormal | **Right eye OELAT** | **€** Normal | **€** Abnormal |
| **If abnormal, describe[[121]](#footnote-121) OEORRES** |  |  |

1. Recommended follow-up after treatment is at 3 and 6 months [↑](#footnote-ref-1)
2. UNK=Unknown [↑](#footnote-ref-2)
3. CD4 counts from patient’s ART book can be captured here [↑](#footnote-ref-3)
4. CD4 counts as part of the medical history. Baseline CD4 count is captured later in the CRF. [↑](#footnote-ref-4)
5. Viral load as part of the medical history. Baseline viral load is captured later in the CRF. [↑](#footnote-ref-5)
6. QD=once daily; QM=every month. These are suggestions only, others include BID twice daily; TID= three times a day; QID=four times a day; PRN=as needed; U=unknown [↑](#footnote-ref-6)
7. PO=oral; IM=intramuscular; IV=intravenous. These are suggestions others include transdermal, intraocular, inhalation, intra-lesion, intraperitoneal, nasal, vaginal [↑](#footnote-ref-7)
8. PKDL grading is currently only used in Africa, mainly Sudan but included here as an example as could be a useful tool for other regions. If grading scales are used these will be defined in the protocol [↑](#footnote-ref-8)
9. Mild (Grade 1): scattered macular, papular or nodular rash on the face with or without lesions on the upper chest or arms [↑](#footnote-ref-9)
10. Moderate (Grade 2): dense macular. papular or nodular rash covering most of the face and extending to the chest, back, upper arms and legs; with only scattered lesions on the forearms and legs [↑](#footnote-ref-10)
11. Severe (Grade 3): dense maculopapular or nodular rash covering most parts of the body, including the hands and feet; the mucosa of the lip and palate may be involved. [↑](#footnote-ref-11)
12. If there is a risk of a change in pregnancy test kit during the study, manufacturer, trade name and lot number (from the DI CDISC domain) need to be included at the individual patient level and recorded on the CRF [↑](#footnote-ref-12)
13. Males [↑](#footnote-ref-13)
14. Hysterectomy, bilateral salpingectomy, and bilateral oophorectomy [↑](#footnote-ref-14)
15. For data management, not for inclusion in SDTM [↑](#footnote-ref-15)
16. The units of measure are an example, the protocol will specify which unit’s the ECG parameters are to be recorded [↑](#footnote-ref-16)
17. The study protocol may require a calculated adjustment for the QT interval, this will be generated in the analysis, and the corrected result and method of correcting included in the analysis considerations section of the VL standard user guide [↑](#footnote-ref-17)
18. In some countries local privacy law may not allow DOB, in this instance age should be used [↑](#footnote-ref-18)
19. If actual date is unknown use 99 or 999 for place holder for ANY day and month [↑](#footnote-ref-19)
20. Only record age if DOB unknown, if child aged less than 5 years record in months, if older than 5 years record in years [↑](#footnote-ref-20)
21. As recommended by FDA, see VL Standard user guide [↑](#footnote-ref-21)
22. The CDASH variable CRACE (Collected Race) is used in addition to the variable RACE (Race) when more detailed race categorizations are desired (e.g., use of race designations other than those used by the FDA). For additional guidance using this variable please refer to the CDASHIG v2.0 and the SDTMIG v3.2. See controlled terminology for full code-list of race as collected [https://evs.nci.nih.gov/ftp1/CDISC/SDTM/] [↑](#footnote-ref-22)
23. For data management, not for inclusion in SDTM [↑](#footnote-ref-23)
24. If the actual date is unknown use 99 or 999 as a place holder for ANY day and month [↑](#footnote-ref-24)
25. These conditions captured are not exhaustive and can be adapted per study protocol [↑](#footnote-ref-25)
26. The grading will be specified in the study protocol [↑](#footnote-ref-26)
27. Previous medication duration will be specified in the study protocol [↑](#footnote-ref-27)
28. Self-reported signs and symptoms of VL at diagnosis [↑](#footnote-ref-28)
29. The grading will be specified in the study protocol [↑](#footnote-ref-29)
30. Some site might calculate weight-for-age, height-for-age and weight-height-for-age using a standard such as WHO growth curves; these might further be used to classify a nutritional status such as malnutrition and severe malnutrition. In these instances, the z score cut-off used for classification of nutritional status will be defined in the protocol [↑](#footnote-ref-30)
31. Malnutrition and severe malnutrition will be defined in the study protocol [↑](#footnote-ref-31)
32. If the actual date is unknown use 99 or 999 as a place holder for ANY day and month [↑](#footnote-ref-32)
33. The laboratory tests and units shown above are an example, use the laboratory tests and units specified in the protocol [↑](#footnote-ref-33)
34. The units of measure are an example, the protocol will specify which unit’s lab. values to be recorded in [↑](#footnote-ref-34)
35. Clinical significance will be specified in the protocol [↑](#footnote-ref-35)
36. The laboratory tests and units shown above are an example, use the laboratory tests and units specified in the protocol, others to consider could be alkaline phosphatase and indirect bilirubin [↑](#footnote-ref-36)
37. The units of measure are an example, the protocol will specify which unit’s laboratory values to be recorded in [↑](#footnote-ref-37)
38. Clinical significance will be specified in the protocol [↑](#footnote-ref-38)
39. For data management, not for inclusion in SDTM [↑](#footnote-ref-39)
40. If there is a risk of a change in pregnancy test kit during the study, manufacturer, trade name and lot number (from the DI CDISC domain) need to be included at the individual patient level and recorded on the CRF [↑](#footnote-ref-40)
41. Hysterectomy, bilateral salpingectomy, and bilateral oophorectomy [↑](#footnote-ref-41)
42. The units of measure are an example, the protocol will specify which unit’s laboratory values to be recorded in [↑](#footnote-ref-42)
43. RDT=rapid diagnostic test [↑](#footnote-ref-43)
44. HIV1AB=HIV-1 Antibody, HIV1AG=HIV-1 Antigen [↑](#footnote-ref-44)
45. HIV124AG=HIV-1 p24 Antigen, HIV12P24=HIV-1/2 Antibody + HIV-1 p24 Antigen, HIV1AB24=HIV-1 Antibody + HIV-1 p24 Antigen [↑](#footnote-ref-45)
46. The units of measure are an example, the protocol will specify which unit’s laboratory values to be recorded in [↑](#footnote-ref-46)
47. RDT=rapid diagnostic test [↑](#footnote-ref-47)
48. DAT=direct agglutination test [↑](#footnote-ref-48)
49. IFAT-indirect immunofluorescent antibody test [↑](#footnote-ref-49)
50. ELISA=enzyme-linked immunosorbent assay [↑](#footnote-ref-50)
51. 6+ > 100 parasites per field; 5+ 10-100 parasites per field; 4+ 1-10 parasites per field; 3+ 1-10 parasites per 10 fields; 2+ 1-10 parasites per 100 fields; 1+ 1-10 parasites per 1000 fields; 0 = 0 parasite per 1000 fields . Note grading of parasites is only relevant in spleen and bone marrow samples, the definitions of grading need to be included in the metadata. [↑](#footnote-ref-51)
52. For data management, not for inclusion in SDTM [↑](#footnote-ref-52)
53. AFB = acid Fast Bacilli, MTB = Mycobacterium Tuberculosis, MTBCMPLX = Mycobacterium Tuberculosis Complex, LAM = Lipoarabinomannan, IFNG = Interferon Gamma [↑](#footnote-ref-53)
54. RERESTRG was proposed as part of the TB TAUG, please refer to the TAUG-TB v2.0, p.30, for more information https://www.cdisc.org/standards/therapeutic-areas/tuberculosis [↑](#footnote-ref-54)
55. RERESTRG was proposed as part of the TB TAUG, please refer to the TAUG-TB v2.0, p.30, for more information https://www.cdisc.org/standards/therapeutic-areas/tuberculosis [↑](#footnote-ref-55)
56. For studies that require the slide to be read by more than one microscopist, include a separate row for the results from each reader. [↑](#footnote-ref-56)
57. Complete a separate row for smears showing both asexual and sexual parasites. Adapt if additional information on the staging of the asexual parasite may be required by the study protocol; e.g. Rings, Trophozoites, Schizonts [↑](#footnote-ref-57)
58. In SDTM the malaria species and parasite type will be concatenated (linked together) and represented in MBTESTCD/TEST [↑](#footnote-ref-58)
59. Record the actual parasite count; see TAUG-malaria for additional information on then calculating parasite density. [↑](#footnote-ref-59)
60. The preferred method of calculating parasite density uses actual WBC/uL; some study protocols may specify assuming (xxx) WBC/uL; see TAUG-malaria for additional information. [↑](#footnote-ref-60)
61. In cases of mixed infections, all infecting species must be reported; however, the asexual and/or sexual parasite count need not be reported separately for each species unless specifically required in the study protocol. If species are reported separately, counts for each species must be entered on separate lines. Asexual and sexual stages from the same slide/parasite species also must be entered on separate lines. [↑](#footnote-ref-61)
62. Record each dose of study medication given; if a dose is re-administered after initial dose was vomited this will be recorded in a new row in SDTM (see user guide) [↑](#footnote-ref-62)
63. If study drug is interrupted due to rescue treatment, record in concomitant medications module [↑](#footnote-ref-63)
64. QD=once daily; BID twice daily; TID= three times a day; QID=four times a day. These are suggestions only the frequency of oral dose administration will be specified in the protocol [↑](#footnote-ref-64)
65. Clinical guide only, not for submission [↑](#footnote-ref-65)
66. QD=daily; BID= twice daily. These are suggestions only the frequency of oral dose administration will be specified in the protocol [↑](#footnote-ref-66)
67. IV=intravenous; IM=intramuscular [↑](#footnote-ref-67)
68. If study treatment is interrupted and restarted, enter details on new row of study treatment [↑](#footnote-ref-68)
69. Data for ART compliance/adherence can be captured in many different ways, the CRF structure is for guidance and this can be adapted as required per protocol. [↑](#footnote-ref-69)
70. UNK=unknown [↑](#footnote-ref-70)
71. INH = Isoniazid, RIF = Rifampin, PZA = Pyrazinamide, EMB = Ethambutol, SM = Streptomycin [↑](#footnote-ref-71)
72. UNK = unknown [↑](#footnote-ref-72)
73. This section is for clinical guidance only, if PKDL is detected during the follow-up period or PKDL was present at baseline and has worsened on physical examination, **PETERM = PKDL,** details need to be captured in the AE module [↑](#footnote-ref-73)
74. Not applicable, PKDL an exclusion criteria [↑](#footnote-ref-74)
75. Worsened could be mild/moderate at baseline and assessed as moderate/severe at follow-up [↑](#footnote-ref-75)
76. Some sites might use a severity grading such as the example included, see user guide for additional detail [↑](#footnote-ref-76)
77. scattered macular, papular or nodular rash on the face with or without lesions on the upper chest or arms (Grade 1) [↑](#footnote-ref-77)
78. dense macular. papular or nodular rash covering most of the face and extending to the chest, back, upper arms and legs; with only scattered lesions on the forearms and legs (Grade 2) [↑](#footnote-ref-78)
79. dense maculopapular or nodular rash covering most parts of the body, including the hands and feet; the mucosa of the lip and palate may be involved (Grade 3) [↑](#footnote-ref-79)
80. This section is intended for clinical guidance, not for submission; the study drug treatment will be stopped, and the details of rescue medication will be recorded as **CMCAT=rescue**, see concomitant and prior medications module [↑](#footnote-ref-80)
81. QD=once daily; BID twice daily; TID= three times a day; QID=four times a day. These are suggestions only, others include QM=every month; PRN=as needed; U=unknown [↑](#footnote-ref-81)
82. PO=oral; IM=intramuscular; IV=intravenous. These are suggestions others include transdermal, intraocular, inhalation, intra-lesion, intraperitoneal, nasal, vaginal [↑](#footnote-ref-82)
83. For data management, not for inclusion in SDTM [↑](#footnote-ref-83)
84. Toxicity grade according to a standard toxicity scale such as CTCAE (Common Terminology Criteria for Adverse Events). The name of the scale and the version should be mentioned in the metadata. [↑](#footnote-ref-84)
85. If classified as serious, please complete a SAE CRF [↑](#footnote-ref-85)
86. Visits outside of routine study visits as defined in the protocol [↑](#footnote-ref-86)
87. If SAE is fatal, date of death will be the same as end date of AE [↑](#footnote-ref-87)
88. The period for reporting concomitant medications will be specified in the protocol [↑](#footnote-ref-88)
89. Units provided are for guidance only and can be adapted per protocol. Pt\_br = British pint/Imperial pint – 20 fluid ounces, 34.678 cubic inches or approximately 568.261 milliliters, Pt\_us = US pint – 16 fluid ounces or 28.875 cubic inches or approximately 473.177 milliliters. [↑](#footnote-ref-89)
90. List any prescription/non-prescription/traditional meds, vitamins, herbal/dietary supplements, or vaccinations given, if none were given check No for “Was any medication given?” [↑](#footnote-ref-90)
91. If concomitant medications were given, enter full trade or generic names [↑](#footnote-ref-91)
92. QD=once daily; BID twice daily; TID= three times a day; QID=four times a day. These are suggestions only, others include QM=every month; PRN=as needed; U=unknown [↑](#footnote-ref-92)
93. PO=oral; TOP=topical; SC=subcutaneous; IM=intramuscular; IV=intravenous; PR=per rectal. These are suggestions others include transdermal, intraocular, inhalation, intra-lesion, intraperitoneal, nasal, vaginal [↑](#footnote-ref-93)
94. The initial outcomes are recommendations and can be adapted on a study basis [↑](#footnote-ref-94)
95. Based on follow-up discussion from the VL study outcome working group [↑](#footnote-ref-95)
96. Follow up duration can be determined on a study by study basis [↑](#footnote-ref-96)
97. This date relates to last contact date in lost-to-follow-up, last study visit. Date of last study visit if withdrawn by participant or investigator, date of death if participant died and last study visit date for other. [↑](#footnote-ref-97)
98. Treatment is defined as primary endpoint. However, it doesn’t preclude overall response being repeated for a secondary endpoint at a later date [↑](#footnote-ref-98)
99. UNK = unknown [↑](#footnote-ref-99)
100. NA = not applicable [↑](#footnote-ref-100)
101. ht = height [↑](#footnote-ref-101)
102. LMP=Last Menstrual Period [↑](#footnote-ref-102)
103. Some studies might use a hearing grading score to determine the severity of hearing loss, this grading category will be specified in the protocol, see VL data standard user guide for additional information [↑](#footnote-ref-103)
104. For data management, not for inclusion in SDTM [↑](#footnote-ref-104)
105. NA = not applicable (not required for this study protocol) [↑](#footnote-ref-105)
106. The specific frequency in Hz will be specified in the protocol and could range from 125 Hz – 8000 Hz, these are examples to be replaced by protocol specified thresholds [↑](#footnote-ref-106)
107. The units of measure are an example, the protocol will specify which unit’s the hearing parameters are to be recorded in [↑](#footnote-ref-107)
108. Some sites may will use a grading to determine level of hearing in each ear, such as grading table included [↑](#footnote-ref-108)
109. The analyte name, drug concentration results and units of measure will be a direct upload as an excel/csv file from the pharmacology laboratory responsible for these assays [↑](#footnote-ref-109)
110. For data management, not for inclusion in SDTM [↑](#footnote-ref-110)
111. NA = not applicable (not required for this study protocol) [↑](#footnote-ref-111)
112. The specific time-points will be documented in the protocol [↑](#footnote-ref-112)
113. If more than one radiology procedure done, list each on a separate row on CRF [↑](#footnote-ref-113)
114. Pocus = Point of Care Ultrasound [↑](#footnote-ref-114)
115. Manufacturer, batch number and trade name will be specified in the study protocol and included in SDTM [↑](#footnote-ref-115)
116. For data management, not for inclusion in SDTM [↑](#footnote-ref-116)
117. NA = not applicable (not required for this study protocol) [↑](#footnote-ref-117)
118. For data management, not for inclusion in SDTM [↑](#footnote-ref-118)
119. NA = not applicable (not required for this study protocol) [↑](#footnote-ref-119)
120. Ophthalmic examination result provides information on any specific abnormalities observed during the anterior segment examination e.g. red spot visible [↑](#footnote-ref-120)
121. Overall interpretation finding from the anterior segment examination [↑](#footnote-ref-121)