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TEMPLATE: Case Record Form for chronic Chagas Disease

Annotated Case Record Form (CRF) for use in clinical studies in patients with Indeterminate

Chronic Chagas Disease

Version 1.0, Mar. 2024

**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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| **Notes**: This is a CDISC compliant CRF so the format is dictated by CDISC. The CRF is divided into sections which we will call ‘module.’ The aim is to order the modules chronologically by visit where possible but also allow room for the study investigator to pick and choose modules at each visit. | | | | | | | | |
|  | | **DATA MODULE** | | | | | | |
| **DAY -7 to Day 0/VISIT 1[[1]](#footnote-1)** | | [Eligibility Assessment and Randomisation](#_heading=h.1fob9te) | | | | | | |
| [Demographics](#_heading=h.3znysh7) | | | | | | |
| Travel History & [Risk](#_heading=h.1t3h5sf) Factors | | | | | | |
| Pregnancy Status and Testing | | | | | | |
| [Chagas Disease Diagnosis (Serology & PCR)](#_heading=h.3dy6vkm) | | | | | | |
| [Treatment History of Chagas Disease](#_heading=h.4d34og8) | | | | | | |
| [Medical and Surgical History](#_heading=h.17dp8vu) | | | | | | |
| [Vital Signs](#_heading=h.3rdcrjn) | | | | | | |
| [Physical Examination](#_heading=h.lnxbz9) | | | | | | |
| [ECG Recording](#_heading=h.35nkun2) | | | | | | |
| [Laboratory Results (Haematology and Biochemistry)](#_heading=h.1ksv4uv) | | | | | | |
| **VISIT 1 & FOLLOW-UP DAYS[[2]](#footnote-2)** | | [Study Drug Administration](#_heading=h.2jxsxqh) | | | | | | |
| [Study Drug Accountability](#_heading=h.3j2qqm3) | | | | | | |
| [Adverse Events, Serious Adverse Events and Medically Attended Adverse Events](#_heading=h.1y810tw) | | | | | | |
| [Concomitant Medications](#_heading=h.2xcytpi) | | | | | | |
| **DISPOSITION** | | [Patient Visit Status and Overall Disposition](#_heading=h.1ci93xb) | | | | | | |
| **APPENDICES** | | 1. [Pharmacokinetic Sampling](#_heading=h.3whwml4) | | | | | | |
| 1. [Echocardiography Testing](#_heading=h.1pxezwc) | | | | | | |
| 1. [Holter Testing](#_heading=h.2bn6wsx) | | | | | | |
| 1. [Cardiac MRI](#_heading=h.qsh70q) | | | | | | |
| 1. [Detailed Pregnancy Status](#_heading=h.3as4poj) | | | | | | |
| 1. [Hepatitis Testing](#_HEPATITIS_TESTING_[MB]) | | | | | | |
| 1. [HIV Status](#_HIV_TESTING_[MB]) | | | | | | |
| 1. [General Biomarker](#_GENERAL_BIOMARKER_[MB]) | | | | | | |
| **SCREENING VISIT (Day -7 to Day 1)** | | | | | | | |
| **Date of screening**  **VISDAT** | | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]** | | | | |
| **Time of screening VISTIM** | | | |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | | | | |
| **ELIGIBILITY ASSESSMENT [IE]** | | | | | | | |
| **Inclusion CriteriaIETEST  (IECAT = INCLUSION)** | **Criterion Description [Adapt as per protocol]** | | | | | **Yes** | **No** |
| **IEORRES** | |
| INCL001 | Informed consent obtained | | | | | **□** | **□** |
| INCL002 | Diagnosis of T. cruzi infection by conventional serology (a minimum of two positive tests [conventional ELISA, recombinant ELISA, chemiluminescense immunoassay, IIF]) | | | | | **□** | **□** |
| INCL003 | A positive PCR result | | | | | **□** | **□** |
| INCL004 | Ability to comply with all protocol specified tests and visits and / or have a permanent address | | | | | **□** | **□** |
| INCL005 | **Criterion Description [Adapt as per protocol]** | | | | | **□** | **□** |
| **Exclusion Criteria**  **IETEST  (IECAT = EXCLUSION)** | **Criterion Description [Adapt as per protocol]** | | | | | **Yes** | **No** |
| **IEORRES** | |
| EXCL001[[3]](#footnote-3) | Acute or chronic health conditions, that in the opinion of the PI, may interfere with the efficacy and / or safety evaluation of the study drug (such as acute infections, history of HIV infection, liver and renal disease  requiring treatment). | | | | | **□** | **□** |
| EXCL002 | Condition that prevents patient from taking oral medication. | | | | | **□** | **□** |
| EXCL003 | Pregnant women. | | | | | **□** | **□** |
| EXCL004 | Patients with previous history of hypersensitivity reaction or known drug class allergy to any of the study treatments. | | | | | **□** | **□** |
| EXCL005 | Adults with organ damage. | | | | | **□** | **□** |
| **Assessment of eligibility at VISIT 1** | | | | | | **Yes** | **No** |
| **Did the subject meet all eligibility criteria? IEYN** | | | | | | **□** | **□** |
| **If no, specify criteria number not met IETESTCD** | | | |  | | | |
| **Date and time informed consent given**  **DSDECOD = INFORMED CONSENT** | | | | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY] DSSTDAT RFICDTC[[4]](#footnote-4)** | **|\_\_|\_\_|:|\_\_|\_\_| [HH:MM] DSSTTIM RFICDTIM** | | |

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| **RANDOMISATION [DS] ARM DSDECOD = RANDOMIZED DSCAT = PROTOCOL MILESTONE** | |
| **Date of randomisation VISDAT DSSTDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]** |
| If applicable, to which group is the participant randomised (ie randomisation code)? **ARM ARMCD** |  |

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| **DEMOGRAPHICS** **[DM]** | | | | | | | | |
| **Date of completion DMDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **[DD-MMM-YYYY] VISDAT** | | **Time of completion VISTIM** | | | |\_\_|\_\_|:|\_\_|\_\_|  **[HH:MM]** | | |
| **What is the patient’s date of birth?[[5]](#footnote-5) [[6]](#footnote-6) BRTHDAT BRTHDTC** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY]** | | | | | | | |
| **OR, if BRTHDAT unknown,**  **what is the patient’s age?[[7]](#footnote-7)** | **|\_\_|\_\_|\_\_| AGE** | | **□** Weeks  **AGEU** | | **□** Months **AGEU** | | | **□** Years  **AGEU** |
| **What is the patient’s sex at birth? SEX** | **□** Male | **□** Female |  | | | | | |
| **What is the race of the subject[[8]](#footnote-8)?**  **RACEC[[9]](#footnote-9) RACE** | **** Black  **** White  **** Latin American  **** Asian  **** Other | | | | | | | |
| **If other, specify RACEOTH** |  | | | | | | | |
| **What is the patient’s nationality? (check all) SCTEST** | **SCORRES** | | | | | | | |
| **What is the patient’s place of birth? SCTEST** | Country **SCORRES** | City **SCORRES** | | Commune **SCORRES** | | | **□** Rural **SCTEST = Dwelling Type**  **□** Urban **SCTEST = Dwelling Type** | |
| **Where is the patient currently living? SCTEST** | Country **SCORRES** | City **SCORRES** | | Commune **SCORRES** | | | **□** Rural **SCTEST = Dwelling Type**  **□** Urban **SCTEST = Dwelling Type** | |

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| **TRAVEL & MIGRATION HISTORY [ER]**  **ERCAT = CHAGAS DISEASE RISK FACTORS** | | | | | | | | | | | |
| **Date of completion VISDAT ERDTC** | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]** | | | | **Time of completion VISTIM ERDTC** | | | |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | | |
| **Has patient ever lived in a different region other than where they are currently living? (if yes, please see below)  ERTERM = INTERNATIONAL TRAVEL** | | | | | | | | **□** Yes  **EROCCUR** | **□** No **EROCCUR** | | **□** Unknown  **EROCCUR** |
| **Country**   **FAORRES** | **City** **FAORRES** | | **Commune** **FAORRES** | **Rural** | **Urban** | | **Arrival date**  **ERSTDTC** | | | **Departure date** **ERENDTC** | |
|  |  | |  | **□** | **□** | | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  [DD-MMM-YYYY]** | | | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  [DD-MMM-YYYY]** | |
|  |  | |  | **□** | **□** | | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  [DD-MMM-YYYY]** | | | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  [DD-MMM-YYYY]** | |

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| **RISK FACTORS [ER] ERCAT = CHAGAS DISEASE RISK FACTORS** | | | | | | |
| **Date of completion VISDAT ERDTC** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY]** | **Time of completion VISTIM ERDTC** | | | **|\_\_|\_\_|:|\_\_|\_\_| [HH:MM]** | |
| **Did your mother ever have Chagas disease? ERTERM** | | | | **□** Yes **EROCCUR** | **□** No **EROCCUR** | **□** Unknown **EROCCUR** |
| **Have you ever lived with a family member who has been diagnosed with Chagas disease? ERTERM** | | | | **□** Yes **EROCCUR** | **□** No **EROCCUR** | **□** Unknown **EROCCUR** |
| **Do you recall ever observing kissing bugs? ERTERM** | | | | **□** Yes **EROCCUR** | **□** No **EROCCUR** | **□** Unknown **EROCCUR** |
| **Do you recall observing kissing bugs in your current home? ERTERM** | | | | **□** Yes **EROCCUR** | **□** No **EROCCUR** | **□** Unknown **EROCCUR** |
| **In the past, have you lived in a house where there were kissing bugs? ERTERM** | | | | **□** Yes **EROCCUR** | **□** No **EROCCUR** | **□** Unknown **EROCCUR** |
| **Has your house ever been sprayed with insecticides? ERTERM** | | | | **□** Yes **EROCCUR** | **□** No **EROCCUR** | **□** Unknown **EROCCUR** |
| **Do you currently live in a house with any of the following characteristics? ERTERM** | | | **□** Mud  **FAORRES** | **□** Adobe walls  **FAORRES** | **□** Thatch roofs  **FAORRES** | **□** None of the above  **FAORRES** |
| **Have you observed kissing bugs while travelling? ERTERM** | | | | **□** Yes **EROCCUR** | **□** No **EROCCUR** | **□** Unknown **EROCCUR** |
| **Have you travelled to an area where it is known to have kissing bugs? ERTERM** | | | | **□** Yes **EROCCUR** | **□** No **EROCCUR** | **□** Unknown **EROCCUR** |
| **Have you ever had a blood transfusion (if yes, please complete medical history section)? ERTERM** | | | | **□** Yes **EROCCUR** | **□** No **EROCCUR** | **□** Unknown **EROCCUR** |
| **Have you ever had a transplant (if yes, please complete medical history section)? ERTERM** | | | | **□** Yes **EROCCUR** | **□** No **EROCCUR** | **□** Unknown **EROCCUR** |

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| **PREGNANCY STATUS [RP]** ***Only applicable to women of child-bearing potential, as defined in the protocol*** | | | | |
| **Date of completion VISDAT RPDTC** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY]** | | **Time of completion VISTIM RPDTC** | **|\_\_|\_\_|:|\_\_|\_\_| [HH:MM]** |
| **Is patient of child-bearing potential  RPTEST = Childbearing Potential**  **RPTESTCD = CHILDPOT** | | | **□** Yes **RPORRES** | **□** No **RPORRES** |
| **If No, please check** | | | **□** Surgically sterile[[10]](#footnote-10) **RPTEST = Surgically Sterile Indicator**  **□** Menopause **RPTEST = Menopause Status**  **□** Other, specify | |
| **Is the patient currently breastfeeding RPTEST=Subj Currently Breastfeeding a Child Ind RPTESTCD=SCBFCIND** | | | **□** Yes **RPORRES** | **□** No **RPORRES** |
| **Is patient using any birth control RPTESTCD = BCMETHOD** | | | **□** Yes | **□** No |
| **If yes, please check all that apply RPORRES where RTESTCD = BCMETHOD** | | | **□** Combined Hormonal Contraceptives[[11]](#footnote-11)  **□** Progesterone-only Contraceptives  **□** Intrauterine Device  **□** Barrier method  **□** Other | If other, please specify |
| **Is the subject pregnant?**  **RPTEST = Pregnant During the Study**  **RPTESTCD = PREGST** | | **□** Yes **RPORRES**  **□** No **RPORRES**  **□** UNK[[12]](#footnote-12) **RPORRES**  **□** NA[[13]](#footnote-13) **RPORRES** | **Date of last menstrual period (LMP) RPTEST= Last Menstrual Period Start Date**  **RPTESTCD = LMPSTDTC** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  [DD-MMM-YYYY]**  **RPORRES where RPTEST = Last Menstrual Period Start Date** |
| **RPORRES where RPTEST = Pregnant During the Study** |  | |

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| **PREGNANCY TESTING [LB] *Only applicable to women of child-bearing potential, as defined in the protocol*** | | | | | | | | |
| **Was a sample taken for pregnancy testing?** **LBPREFYN** | **□** Yes | **□** No | **□** NA[[14]](#footnote-14) | **Specimen type LBSPEC** | **□** Urine  **□** Blood | **Date of sample collection LBDAT LBDTC** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  [DD-MMM-YYYY]** | |
| **Pregnancy test name**  **LBTEST** | **Not done**  **LBSTAT** | | **Reason not done  LBREASND** | | | **Result LBORRES** | | |
|  | **□** | | **□** Pre-menarche  **□** Permanently sterile**[[15]](#footnote-15)**  **□** Postmenopausal  **□** Refused test  **□** Other, specify below | | | **□** Negative | | **□** Positive |

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| **CHAGAS DISEASE DIAGNOSTIC TEST – SEROLOGY [MB]** | | | | | | | | | |
| **ELISA, Conventional [MB] MBMETHOD = ELISA MBTEST = Trypanosoma cruzi Antibody MBTESTCD = TCRZIAB REPEAT AS PER PROTOCOL** | | | | | | | | | |
| **Was a conventional ELISA test performed? MBPERF** | **□** Yes | **□** No | **Not done MBSTAT** | **□** | **Reason not done MBREASND** | | |  | |
| **Collection date and time**  **MBDAT MBDTC** | **Sample type MBSPEC** | | **Trade name  DIVAL when DIPARM=Trade Name** | **Batch number**  **DIVAL when DIPARM = Lot Name** | **Optical density** | **Optical density unit** | **Cut off** | **Quantitative results MBORRES  MBTSTDTL = QUANTIFICATION** | **Qualitative Results MBORRES  MBTSTDTL = DETECTION** |
| **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  [DD-MMM-YYYY]**  **|\_\_|\_\_|:|\_\_|\_\_| [HH:MM]** | **□** Venous blood  **□** Other (describe below) | | **□** \_\_\_  **□** Other (describe below) |  |  | OD unit |  |  | **□** Positive  **□** Negative  **□** Indeterminate |
| **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  [DD-MMM-YYYY]**  **|\_\_|\_\_|:|\_\_|\_\_| [HH:MM]** | **□** Venous blood  **□** Other (describe below) | |  |  |  | OD unit |  |  | **□** Positive  **□** Negative  **□** Intermediate |

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| **ELISA, Recombinant [MB] MBMETHOD = T CRUZI RECOMBINANT ELISA MBTEST = Trypanosoma cruzi Antibody MBTESTCD = TCRZIAB REPEAT AS PER PROTOCOL** | | | | | | | | | |
| **Was a recombinant ELISA test performed? MBPERF** | **□** Yes | **□** No | **Not done MBSTAT** | **□** | **Reason not done MBREASND** | | |  | |
| **Collection date and time**  **MBDAT MBDTC** | **Sample type MBSPEC** | | **Trade name  DIVAL when DIPARM=Trade Name** | **Batch number**  **DIVAL when DIPARM=Lot Name** | **Optical density FAORRES** | **Optical density unit FAORRESU** | **Cut off** | **Quantitative results MBORRES  MBTSTDTL = QUANTIFICATION** | **Qualitative Results  MBORRES  MBTSTDTL = DETECTION** |
| **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  [DD-MMM-YYYY]**  **|\_\_|\_\_|:|\_\_|\_\_| [HH:MM]** | **□** Venous blood  **□** Other (describe below) | | **□** \_\_\_  **□** Other (describe below) |  |  | OD unit |  |  | **□** Positive  **□** Negative  **□** Indeterminate |
| **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  [DD-MMM-YYYY]**  **|\_\_|\_\_|:|\_\_|\_\_| [HH:MM]** | **□** Venous blood  **□** Other (describe below) | |  |  |  | OD unit |  |  | **□** Positive  **□** Negative  **□** Intermediate |

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| **PCR [MB] MBMETHOD = REAL-TIME POLYMERASE CHAIN REACTION ASSAY MBTEST = Trypanosoma cruzi MBTESTCD = TCRZI**  **REPEAT AS PER PROTOCOL** | | | | | | | | | | | |
| **Was a sample taken for PCR? MBPERF** | **□** Yes | **□** No | **Not done MBPERF MBSTAT** | **□** | **Reason not done MBREASND** |  | | **Sample type MBSPEC** | | **□** Venous blood  **□** Other (describe below) **MBSPREOTH** | **Amount of blood collected (mL) FAORRES FAORRESU = mL** |
|  |
| **Collection date and time**  **MBDAT MBDTC**  **MBTIM MBDTC** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY]**  **|\_\_|\_\_|:|\_\_|\_\_| [HH:MM]** | | | | **Primers used MBMETHOD** | **□**  **□** Other (describe below) **MBMETHODOTH** | | | | **Sample ID MBREFID** |  |
| **Trade name**  **DIVAL when DIPARM=Trade Name** | **Lot number**  **DIVAL when DIPARM = Lot Name** | | **Results quantitative (CT value) MBORRES\_QUAN MBTSTDTL = QUNATIFICATION CYCLE NUMBER** | | | **Units of measure MBORRESU\_QUAN** | **Results qualitative MBORRES\_QUAL MBTSTDTL = DETECTION** | | | | |
| **□** \_\_\_  **□** Other (describe below) |  | |  | | |  | **□** Positive  **□** Negative  **□** Indeterminate | | | | |
| **□** \_\_\_  **□** Other (describe below) |  | |  | | |  | **□** Positive  **□** Negative  **□** Indeterminate | | | | |
| **□** \_\_\_  **□** Other (describe below) |  | |  | | |  | **□** Positive  **□** Negative  **□** Indeterminate | | | | |
| **Overall result of PCR? MBORRES MBTSTDTL = DETECTION** | | | **□** Positive | | | **□** Negative | | | **□** Indeterminate | | |

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| **TREATMENT HISTORY OF CHAGAS [CM]** | | | | | | | | | | |
| **Has the patient ever received etiological or antiparasitic treatment for Chagas disease?**   **CMCAT = PRIOR CMTRT = ANTI-CHAGAS DRUGS** | | | | | | | **□** Yes **CMOCCUR** | **□** No **CMOCCUR** | **□** Unknown **CMOCCUR** | |
| **Are previous treatment regimens for Chagas Disease, known? If yes, please complete below CMYN** | | | | | | | **□** Yes | **□** No | **□** NA | |
| **Date of completion VISDAT CMDTC** | | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]** | | | **Time of completion VISTIM CMDTC** | | | |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | |
| **Start date CMDOSTOT** | **Treatment Given CMTRT** | | **Frequency[[16]](#footnote-16) CMDOSFRQ** | **Dose formulation CMDOSFRM** | **Dose amount CMDOSE** | **Unit  CMDOSU** | **Route of administration CMROUTE** | **End date  CMENDAT CMENDTC** | **Duration of treatment CMDUR** | **If discontinued taking drug, add reason CMRSDISC** |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **[DD-MMM-YYYY]** | **□** BNZ  **□** NFT  **□** Other | | **□** QD  **□** BID | **□** tablet  **□** capsule  **□** susp.  **□** other |  | **□** mg/kg  **□** mL  **□** mg  **□** TABLET | **□** PO  **□** IM  **□** IV | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  [DD-MMM-YYYY]** | **|\_\_|\_\_|**  **Days** |  |
| **Other, specify:** |  |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **[DD-MMM-YYYY]** | **□** BNZ  **□** NFT  **□** Other | | **□** QD  **□** BID | **□** tablet  **□** capsule  **□** susp.  **□** other |  | **□** mg/kg  **□** mL  **□** mg  **□** TABLET | **□** PO  **□** IM  **□** IV | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  [DD-MMM-YYYY]** | **|\_\_|\_\_|**  **Days** |  |
| **Other, specify:** |  |

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| **MEDICAL AND SURGICAL HISTORY [MH]  *Existing prior to admission and ongoing*** | | | | | | |
| **CHAGAS MEDICAL HISTORY** | | | | | | |
| **Date of completion VISDAT MHDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]** | **Time of completion VISTIM MHDTC** | | | |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | |
| **Have you had a history of palpitations MHTERM** | | | | **□** Yes **MHOCCUR** | **□**No **MHOCCUR** | **□** Unknown **MHOCCUR** |
| **Have you had a history of hypertension MHTERM** | | | | **□** Yes **MHOCCUR** | **□**No **MHOCCUR** | **□** Unknown **MHOCCUR** |
| **Have you had a history of dyslipidaemia MHTERM** | | | | **□** Yes **MHOCCUR** | **□**No **MHOCCUR** | **□** Unknown **MHOCCUR** |
| **Have you had a history of autoimmune disease MHTERM** | | | | **□** Yes **MHOCCUR** | **□**No **MHOCCUR** | **□** Unknown **MHOCCUR** |
| **Have you had a history of swelling of legs and feet MHTERM** | | | | **□** Yes **MHOCCUR** | **□**No **MHOCCUR** | **□** Unknown **MHOCCUR** |
| **Have you had a history of difficulties with food or liquid intake MHTERM** | | | | **□** Yes **MHOCCUR** | **□**No **MHOCCUR** | **□** Unknown **MHOCCUR** |
| **Have you had a history of intestinal transit difficulties (e.g. constipation) MHTERM** | | | | **□** Yes **MHOCCUR** | **□**No **MHOCCUR** | **□** Unknown **MHOCCUR** |
| **Have you had a history of diabetes? MHTERM** | | | | **□** Yes **MHOCCUR** | **□**No **MHOCCUR** | **□** Unknown **MHOCCUR** |
| **Smoking status SUTRT** | | | **□** Current **SUNCF SUOCCUR SUSTRF = CURRENT** | **□** Never Smoked **SUNCF SUOCCUR** | **□** Former smoker **SUNCF SUOCCUR SUSTRF = BEFORE** | **□** Unknown **SUOCCUR** |

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| **GENERAL MEDICAL HISTORY [MH]** | | | | | | | | |
| **Has the patient experienced any concomitant diseases prior to screening?** **MHYN** | | | | **□ Yes** | **□ No** | |  | |
| **Medical condition MHTERM** | **Start date MHSTDAT MHSTDTC** | | | | **End date MHSTDAT MHSTDTC** | | **Or ongoing? MHONGO** | |
|  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **[DD-MMM-YYYY]** | | | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **[DD-MMM-YYYY]** | | **□** | |
| **PRIOR SURGERY & PROCEDURES [PR]** | | | | | | | | |
| **Has the patient received blood transfusion? PRTRT** | **□** Yes | **□** No | **If yes, please provide the year** | | |\_\_|\_\_|\_\_|\_\_| **[YYYY]** | **Please indicate why patient received a blood transfusion PRINDIC** | |  |
| **Does the patient have any clinically significant surgical history? PRYN**  If yes, record below | **□ Yes** | | | | **□ No** | | **□** Unknown | |
| **What is the term for the past surgical procedure? PRTRT** | **Procedure/surgery date PRSTDAT PRSTDTC** | | | | | | | |
|  | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **[DD-MMM-YYYY]** | | | | | | | |
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| **PREVIOUS MEDICATION** **CMCAT=PRIOR** | | |
| **Were any medications taken within the last** **(xx) days prior to participation in the study**[[17]](#footnote-17)?  **The variable EVLINT is used to represent “within the last “xx” days” CMYN30** | **□ Yes** | **□ No** |
| ***If yes, record on the prior medications page (record full trade or generic names)*** | |

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| **PRIOR MEDICATION [CM][[18]](#footnote-18)** | | | | | | | | | |
| **Date of completion VISDAT CMDTC** | | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]** | | **Time of completion VISTIM CMDTC** | | |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | | |
| **Medication**[[19]](#footnote-19)  **CMTRT** | **Dose amount CMDOSAMT** | **Frequency**  **CMDOSU** | **Units**  **CMDOSU** | **Route of administration[[20]](#footnote-20)**  **CMROUTE** | **Start date  CMSTDAT CMSTDTC**  **Start time CMTIM CMSTDTC** | **End date  CMENDAT CMENDTC**  **End time CMENTIM CMENDTC** | **Ongoing? CMONGO CMENRTPT/CMENRF** | **Indication CMINDC** | |
|  |  | **□** QD  **□** BID  **□** TID  **□** Other, specify | **□** mg  **□** TABLET  **□** mL  **□** Other, specify | **□** PO  **□** IM  **□** IV  **□** SC  **□** TOP  **□** Other, specify | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY]**  **|\_\_|\_\_|:|\_\_|\_\_| [HH:MM]** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY]**  **|\_\_|\_\_|:|\_\_|\_\_| [HH:MM]** | **□** |  | |
| **Adverse Event Code?** |  |
|  |  | **□** QD  **□** BID  **□** TID  **□** Other, specify | **□** mg  **□** TABLET  **□** mL  **□** tsp  **□** Other, specify | **□** PO  **□** IM  **□** IV  **□** SC  **□** TOP  **□** Other, specify | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**  **[DD-MMM-YYYY]**  **|\_\_|\_\_|:|\_\_|\_\_| [HH:MM]** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**  **[DD-MMM-YYYY]**  **|\_\_|\_\_|:|\_\_|\_\_| [HH:MM]** | **□** |  | |
| **Adverse Event Code?** |  |

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| **VITAL SIGNS [VS]** | | | | | |
| **Were vital signs performed? VSPERF**[[21]](#footnote-21) | | **□** Yes | | **□** No | |
| **Vital signs collection date VSDAT VSDTC** | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]** | | | |
| **Vital sign measurements[[22]](#footnote-22) VSTEST** | **Results**  **VSORRES** | **Units[[23]](#footnote-23)**  **VSORRESU** | **Not done**  **VSSTAT** | | **Reason not done**  **VSREASND** |
| **Temperature[[24]](#footnote-24)**  **TEMP\_VSTEST VSTESTCD = TEMP VSTEST = Temperature** | **|\_\_|\_\_|.|\_\_|**  **TEMP\_VSORRES** | **°C TEMP\_VSORRESU** | **□** **TEMP\_VSSTAT** | | **TEMP\_VSREASND** |
| **Systolic blood pressure SYSBP\_VSTEST  VSTESTCD = SYSBP VSTEST = Systolic Blood Pressure** | **|\_\_|\_\_|\_\_|**  **SYSBP\_VSORRES** | **mmHg SYSBP\_VSORRESU** | **□ SYSBP\_VSSTAT** | | **SYSBP\_VSREASND** |
| **Diastolic blood pressure DIABP\_VSTEST  VSTESTCD = DIABP VSTEST = Diastolic Blood Pressure** | **|\_\_|\_\_|\_\_|**  **DIABP\_VSORRES** | **mmHg DIABP\_VSORRESU** | **□ DIAPB\_VSSTAT** | | **DIABP\_VSREASND** |
| **Pulse PULSE\_VSTEST VSTESTCD = PULSE VSTEST = Pulse Rate** | **|\_\_|\_\_|\_\_|**  **PULSE\_VSORRES** | **beats/minute PULSE\_VSORRESU** | **□ PULSE\_VSSTAT** | | **PULSE\_VSREASND** |
| **Respiratory rate RESP\_VSTEST VSTESTCD = RESP VSTEST = Respiratory Rate** | **|\_\_|\_\_|**  **RESP\_VSORRES** | **breaths/minute RESP\_VSORRESU** | **□ RESP\_VSSTAT** | | **RESP\_VSREASND** |
| **Weight WEIGHT\_VSTEST VSTESTCD = WEIGHT VSTEST = Weight** | **|\_\_|\_\_|\_\_|.|\_\_|**  **WEIGHT\_VSORRES** | **kg WEIGHT\_VSORRESU** | **□ WEIGHT\_VSSTAT** | | **WEIGHT\_VSREASND** |
| **Height HEIGHT\_VSTEST VSTESTCD = HEIGHT VSTEST = Height** | **|\_\_|\_\_|\_\_|.|\_\_|**  **HEIGHT\_VSORRES** | **cm HEIGHT\_VSORRESU** | **□ HEIGHT\_VSSTAT** | | **HEIGHT\_VSREASND** |
| **Mid upper arm circumference MUAC\_VSTEST VSTESTCD = MUARMCIR VSTEST = Mid-Upper Arm Circumference** | **|\_\_|\_\_|.|\_\_|**  **MUAC\_VSORRES** | **cm MUAC\_VSORRESU** | **□ MUAC\_VSSTAT** | | **MUAC\_VSREASND** |
| **Body Mass Index** **BMI\_VSTEST VSTESTCD = BMI VSTEST = Body Mass Index** | **|\_\_|\_\_|.|\_\_|**  **BMI\_VSORRES** | **kg/m2 BMI\_VSORRESU** | **□** **BMI\_VSSTAT** | | **BMI\_VSREASND** |

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| **PHYSICAL EXAMINATION[[25]](#footnote-25)** **[PE]** | | | | | |
| **Was physical examination performed? PEPERF** | | **□** Yes | | **□** No | |
| **Physical exam date PEDAT PEDTC** | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]** | | | |
| **Body system examined PETEST** | **Result PEORRES** | **If abnormal, please specify** | **Not done PESTAT** | | **Reason not examined PEREASND** |
| **HEENT HEENT\_PETEST PETESTCD = HEENT PETEST = HEAD EYE EAR NOSE THROAT** | **□** Normal  **□** Abnormal ncs  **□** Abnormal cs |  | **□ HEENT\_PESTAT** | | **HEENT\_PEREASND** |
| **Cardiovascular CV\_PETEST PETESTCD = CV PETEST = CARDIOVASCULAR SYSTEM** | **□** Normal  **□** Abnormal ncs  **□** Abnormal cs |  | **□ CVS\_PESTAT** | | **CVS \_PEREASND** |
| **Respiratory RESP\_PETEST PETESTCD = RESP PETEST = RESPIRATORY SYSTEM** | **□** Normal  **□** Abnormal ncs  **□** Abnormal cs |  | **□ PR\_PESTAT** | | **PR\_PEREASND** |
| **Abdominal ABDO\_PETEST PETESTCD = ABDO PETEST = ABDOMEN** | **□** Normal  **□** Abnormal ncs  **□** Abnormal cs |  | **□ ABDO\_PESTAT** | | **ABDO \_PEREASND** |
| **Lymph nodes LYMPH\_PETEST PETESTCD = LYMPH PETEST = LYMPH NODES** | **□** Normal  **□** Abnormal ncs  **□** Abnormal cs |  | **□ LYMPH\_PESTAT** | | **LYMPH\_PEREASND** |
| **Musculoskeletal MUSC\_PETEST PETESTCD = MUSC PETEST = MUSCULOSKELETAL** | **□** Normal  **□** Abnormal ncs  **□** Abnormal cs |  | **□ MUSC\_PESTAT** | | **MUSC\_PEREASND** |
| **Neurological NEURO\_PETEST PETESTCD = NEURO PETEST = NEUROLOGICAL** | **□** Normal  **□** Abnormal ncs  **□** Abnormal cs |  | **□ NEURO\_PESTAT** | | **NEURO\_PEREASND** |
| **Dermatological SKIN\_PETEST PETESTCD = SKIN PETEST = SKIN** | **□** Normal  **□** Abnormal ncs  **□** Abnormal cs |  | **□ SKIN\_PESTAT** | | **SKIN\_PEREASND** |
| **Other OTHER\_PETEST PETESTCD = OTHER PETEST = OTHER ORGANS SYSTEMS** | **□** Normal  **□** Abnormal ncs  **□** Abnormal cs |  | **□ OTHER\_PESTAT** | | **OTHER\_PEREASND** |

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| **ECG RECORDING [EG]** | | | *If the ECG is to be taken more than once at a study time-point (e.g. 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 [[26]](#footnote-26)** | **□** Yes | | **□** No | | **If not done, give reason EGREASND** | | |  | | **Number of ECG EGSEQ** | |  |
| **Date ECG recorded EGDAT EGDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]** | | | | | **Time ECG recorded EGTIM EGDTC** | | | | |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | | |
| **Method EGMETHOD EGMETHOD** | **□** 12 Lead standard **12-LEAD STANDARD** | | | **Position during examination EGPOS EGPOS** | | | | | | **□** SUPINE | | |
| **ECG TEST RESULTS** | | | | | | | | | | | | |
| **ECG test name EGTEST** | | **Results EGORRES** | | | | | **Units[[27]](#footnote-27) EGORRESU** | | **Not done EGSTAT** | | **Reason not done EGREASND** | |
| **Mean Heart Rate EGTESTCD = EGHRMN EGTEST = ECG Mean Heart Rate** | | **|\_\_|\_\_|\_\_| HRMEAN\_EGORRES** | | | | | Beats/min | | **□** | |  | |
| **PR-interval, Aggregate EGTESTCD = PRAG EGTEST = PR Interval, Aggregate** | | **|\_\_|\_\_|\_\_| PRMEAN\_EGORRES** | | | | | msec | | **□** | |  | |
| **Corrected QT-interval[[28]](#footnote-28) , Aggregate EGTESTCD = QTCBAG or QTCFAG EGTEST = QTcB Interval Aggregate or QTcF Interval, Aggregate** | | **|\_\_|\_\_|\_\_| QTMEAN\_EGORRES** | | | | | msec | | **□** | |  | |
| **RR-interval, Aggregate EGTESTCD = RRAG EGTEST = RR Interval, Aggregate** | | **|\_\_|\_\_|\_\_| RRMEAN\_EGORRES** | | | | | msec | | **□** | |  | |
| **QRS-duration, Aggregate  EGTESTCD = QRSAG EGTEST = QRS Duration, Aggregate** | | **|\_\_|\_\_|\_\_| QRSDUR\_EGORRES** | | | | | msec | | **□** | |  | |

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| **Overall ECG Results EGINTP** | **□** Normal | **□** Abnormal | **If Abnormal, please specify** |  | **ECG Result interpretation EGNAM** | **□** Principal investigator  **□** Cardiologist |

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| **Any rhythm or conduction abnormalities** | **□** Yes | **□** No |  |
| **If yes, please see below** | | | |
| **Abnormalities EGORRES** | **□** Heart Rate < 50 Bpm  **□** Atrial Fibrillation **EGORRES where EGTEST = Supraventricular Tachyarrhythmias**  **□** Supraventricular Tachycardia **EGORRES where EGTEST = Supraventricular Tachyarrhythmias**  **□** Premature Atrial Complex **EGORRES where EGTEST = Supraventricular Arrhythmias**  **□** Premature Ventricular Complex **EGORRES where EGTEST = Ventricular Arrhythmias**  **□** 1st Degree AV Block **EGORRES where EGTEST = Atrioventricular Conduction**  **□** 2nd Degree AV Block, Mobitz I **EGORRES where EGTEST = Atrioventricular Conduction**  **□** 2nd Degree AV Block, Mobitz II **EGORRES where EGTEST = Atrioventricular Conduction**  **□** 3rd Degree AV Block **EGORRES where EGTEST = Atrioventricular Conduction**  **□** Right Bundle Branch Block **EGORRES where EGTEST = Intraventricular-Intraatrial Conduction**  **□** Left Bundle Branch Block **EGORRES where EGTEST = Intraventricular-Intraatrial Conduction**  **□** Left Anterior Fascicular Block **EGORRES where EGTEST = Intraventricular-Intraatrial Conduction**  **□** Left Posterior Fascicular Block **EGORRES where EGTEST = Intraventricular-Intraatrial Conduction**  **□** Left Ventricular Hypertrophy **EGORRES where EGTEST = Chamber Hypertrophy or Enlargement**  **□** Right Ventricular Hypertrophy **EGORRES where EGTEST = Chamber Hypertrophy or Enlargement**  **□** Left Atrial Abnormality **EGORRES where EGTEST = Chamber Hypertrophy or Enlargement**  **□** Right Atrial Abnormality **EGORRES where EGTEST = Chamber Hypertrophy or Enlargement**  **□** Other, specify **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | |

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| **LABORATORY RESULTS [LB]** [[29]](#footnote-29) | | | | | | | | | | | |
| **HEMATOLOGY [LB] LBCAT=HEMATOLOGY LBSPEC = BLOOD** | | | | | | | | | | | |
| **Were haematology samples taken**  **LBPERFYN[[30]](#footnote-30)** | | **□** Yes | | **□** No | **□** NA**[[31]](#footnote-31)** | **Date of sample collection LBDAT LBDTC** | | | **Time of sample collection LBTIM LBDTC** | | |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **[DD-MMM-YYYY]** | | | |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM**] | | |
| **Haematology test name LBTEST** | **Results LBORRES** | | **Units[[32]](#footnote-32) LBORRESU** | | | **Was the result interpreted as clinically significant[[33]](#footnote-33) LBSCLSIG** | | **Toxicity grade [[34]](#footnote-34) LBTOXGR** | **Test done  LBSTAT** | | **If no, provide reason LBREASND** |
| **Hemoglobin  LBTESTCD = HGB LBTEST = Hemoglobin** | **|\_\_|\_\_|.|\_\_| HGB\_LBORRES** | | Hb (g/dL) **HGB\_LBORRESU** | | | **□** Yes | **□** No |  | **□** Yes | **□** No |  |
| **White cell count LBTESTCD = WBC LBTEST = Leukocytes** | **|\_\_|\_\_|\_\_|.|\_\_| WBC\_LBORRES** | | WBC (109/L) **WBC\_LBORRESU** | | | **□** Yes | **□** No |  | **□** Yes | **□** No |  |
| **Red cell count LBTESTCD = RBC LBTEST = Erythrocytes** | **|\_\_|\_\_|\_\_|.|\_\_| RBC\_LBORRES** | | RBC (109/L) **RBC\_LBORRESU** | | | **□** Yes | **□** No |  | **□** Yes | **□** No |  |
| **Neutrophils LBTESTCD = NEUT LBTEST = Neutrophils** | **|\_\_|\_\_|.|\_\_| NEUT\_LBORRES** | | Neutrophils (109/L) **NEUT\_LBORRESU** | | | **□** Yes | **□** No |  | **□** Yes | **□** No |  |
| **Basophils LBTESTCD = BASO LBTEST = Basophils** | **|\_\_|\_\_|.|\_\_| BASO\_LBORRES** | | Basophils (109/L) **BASO\_LBORRESU** | | | **□** Yes | **□** No |  | **□** Yes | **□** No |  |
| **Lymphocytes LBTESTCD = LYM LBTEST = Lymphocytes** | **|\_\_|\_\_|.|\_\_| LYM\_LBORRES** | | Lymphocytes (109/L) **LYM\_LBORRESU** | | | **□** Yes | **□** No |  | **□** Yes | **□** No |  |
| **Monocytes LBTESTCD = MONO LBTEST = Monocytes** | **|\_\_|\_\_|.|\_\_| MONO\_LBORRES** | | Monocytes (109/L)  **MONO\_LBORRESU** | | | **□** Yes | **□** No |  | **□** Yes | **□** No |  |
| **Eosinophils LBTESTCD = EOS LBTEST = Eosinophils** | **|\_\_|\_\_|.|\_\_| EOS\_LBORRES** | | Eosinophils (109/L) **EOS\_LBORRESU** | | | **□** Yes | **□** No |  | **□** Yes | **□** No |  |
| **Platelets LBTESTCD = PLAT LBTEST = Platelets** | **|\_\_|\_\_|\_\_|\_\_| PLAT\_LBORRES** | | Platelets (109/L) **PLAT\_LBORRESU** | | | **□** Yes | **□** No |  | **□** Yes | **□** No |  |
| **Haematocrit LBTESTCD = HCT LBTEST = Hematocrit** | **|\_\_|\_\_| HCT\_LBORRES** | | Hematocrit (%)**HCT\_LBORRESU** | | | **□** Yes | **□** No |  | **□** Yes | **□** No |  |

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| **BIOCHEMISTRY [LB]  [[35]](#footnote-35) LBCAT=BIOCHEMISTRY** | | | | | | | | | | |
| **Were biochemistry samples taken? BPERFYN** | | **□** Yes | **□** No | **□** NA[[36]](#footnote-36) | **Date of sample collection LBDAT LBDTC** | | | **Time of sample collection LBTIM LBDTC** | | |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **[DD-MMM-YYYY]** | | | |\_\_|\_\_|:|\_\_|\_\_|  **[HH:MM]** | | |
| **Biochemistry test name LBTEST** | **Results LBORRES** | | **Units[[37]](#footnote-37) LBORRESU** | | **Was the result interpreted as clinically significant[[38]](#footnote-38) LBSCLSIG** | | **Toxicity grade [[39]](#footnote-39) LBTOXGR** | **Test done LBSTAT** | | **If no, provide reason LBREASND** |
| **AST LBTESTCD = AST LBTEST = Aspartate Aminotransferase** | **|\_\_|\_\_|\_\_|\_\_| AST\_LBORRES** | | AST (IU/L) **AST\_LBORRESU** | | **□** Yes | **□** No |  | **□** Yes | **□** No |  |
| **ALT LBTESTCD = AST LBTEST = Aspartate Aminotransferase** | **|\_\_|\_\_|\_\_|\_\_|**  **ALT\_LBORRES** | | ALT (IU/L)  **ALT\_LBORRESU** | | **□** Yes | **□** No |  | **□** Yes | **□** No |  |
| **ALP LBTESTCD = AST LBTEST = Aspartate Aminotransferase** | **|\_\_|\_\_|\_\_|\_\_|**  **ALP\_LBORRES** | | ALP (U/L)  **ALP\_LBORRESU** | | **□** Yes | **□** No |  | **□** Yes | **□** No |  |
| **Total Bilirubin LBTESTCD = BILI LBTEST = Bilirubin** | **|\_\_|\_\_|\_\_|.|\_\_|**  **BILI\_LBORRES** | | Total bilirubin (µmol/L)  **BILI\_ LBORRESU** | | **□** Yes | **□** No |  | **□** Yes | **□** No |  |
| **Direct (Conjugated) Bilirubin LBTESTCD = BILDIR LBTEST = Direct Bilirubin** | **|\_\_|\_\_|\_\_|.|\_\_|**  **BILDIR\_LBORRES** | | Conjugated bilirubin (µmol/L) **BILDIR\_ LBORRESU** | | **□** Yes | **□** No |  | **□** Yes | **□** No |  |
| **Indirect (Unconjugated) Bilirubin LBTESTCD = BILIND LBTEST = Indirect Bilirubin** | **|\_\_|\_\_|\_\_|.|\_\_|**  **BILIND\_LBORRES** | | Unconjugated bilirubin (mg/dL) **BILIND\_LBORRESU** | | **□** Yes | **□** No |  | **□** Yes | **□** No |  |
| **Creatinine LBTESTCD = CREAT LBTEST = Creatinine** | **|\_\_|\_\_|\_\_|\_\_|**  **CREAT\_LBORRES** | | Creatinine (µmol/L)  **CREAT\_LBORRESU** | | **□** Yes | **□** No |  | **□** Yes | **□** No |  |
| **Serum Potassium LBTESTCD = K LBTEST = Potassium** | **|\_\_|.|\_\_|**  **K\_LBORRES** | | Potassium (mmol/L)  **K\_LBORRESU** | | **□** Yes | **□** No |  | **□** Yes | **□** No |  |
| **GGT LBTESTCD = GGT LBTEST = Gamma Glutamyl Transferase** | **|\_\_|\_\_|\_\_| GGT\_LBORRES** | | GGT (U/L) **GGT\_LBORRESU** | | **□** Yes | **□** No |  | **□** Yes | **□** No |  |
| **International-normalised-ratio (INR)  LBTESTCD = INR LBTEST = Prothrombin Intl. Normalized Ratio** | **|\_\_|.|\_\_|  INR\_LBORRES** | | INR (RATIO) **INR\_LBORRESU** | | **□** Yes | **□** No |  | **□** Yes | **□** No |  |
| **Calcium LBTESTCD = CA LBTEST = Calcium** | **|\_\_|\_\_|\_\_|\_\_|**  **CA\_LBORRES** | | Calcium (**mg/dL**) **CA\_LBORRESU** | | **□** Yes | **□** No |  | **□** Yes | **□** No |  |
| **Magnesium LBTESTCD = MB LBTEST = Magnesium** | **|\_\_|\_\_|\_\_|\_\_|**  **MG\_LBORRES** | | Magnesium (**mg/dL) MG\_LBORRESU** | | **□** Yes | **□** No |  | **□** Yes | **□** No |  |
| **Cholesterol LBTESTCD = CHOL LBTEST = Cholesterol** | **|\_\_|\_\_|\_\_|.|\_\_|**  **CHOL\_LBORRES** | | Cholesterol (mmol/L)  **CHOL\_LBORRESU** | | **□** Yes | **□** No |  | **□** Yes | **□** No |  |
| **Glucose LBTESTCD = GLUC LBTEST = Glucose** | **|\_\_|\_\_|\_\_|.|\_\_|**  **GLUC\_LBORRES** | | Glucose (mmol/L)  **GLUC\_LBORRESU** | | **□** Yes | **□** No |  | **□** Yes | **□** No |  |

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| **TREATMENT PHASE** | | | | | | | | | | | | | | | | | | | | | | | | |
| **STUDY DRUG ADMINISTRATION** [[40]](#footnote-40) [[41]](#footnote-41) [**EC]** | | | | | | | | | | | | | | | | | | | | | | | | |
| *This section is an example of how to capture daily study drug administration. Please complete a separate CRF page for each study drug administered* | | | | | | | | | | | | | | | | | | | | | | | | |
| **Date of completion ECDAT ECDTC** | | | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]** | | | | | | **VISIT VISIT** | | | | | | | | |\_\_|\_\_|\_\_| | | | | | | |
| **STUDY MEDICATION RANDOMISATION CODE ECTRT** | | | | | | |  | | | | | | | | | | | | | | | | | |
| **Was study medication given ECOCCUR** | | **Name of drug ECTRT** | | | **Prescribed dose amount ECDOSE\_SCHEDULED ECDOSE ECMOOD = SCHEDULED** | | **Dose units**  **ECDOSU\_SCHEDULED ECDOSU ECMOOD = SCHEDULED** | | **Weight used to calculate dose at Day 1** | | | **Dose formulation ECDOSFRM** | | | **Frequency of dose administration[[42]](#footnote-42) ECDOSFRQ** | | | | | | | | | |
| **□** Yes | **□** No |  | | |  | | □ mg  □ TABLET | | |\_\_|\_\_|.|\_\_|kg | | | □ TABLET  □ CAPSULE | | | **□** QD | | **□** TID | | | **□** BID | | **□** Other, specify | | |
| **EXAMPLE OF A DOSE SCHEDULE** | | | | | | | | | | | | | | | | | | | | | | | | |
| **Date dose administration**  **ECSTDAT ECSTDTC  Time dose administered  ECSTTIM ECSTDTC** | | | **Missed dose? ECOCCUR** | | | **Reason for missed dose**  **ECREASOC** | | **Date dose ended**  **ECENDAT ECENDTC  Time dose ended ECENTIM ECENDTC** | | | **Dose amount given ECDSTXT ECDOSE ECMOOD = PERFORMED** | | | **Dose units**  **ECDOSU ECMOOD = PERFORMED** | | | | | **Route of administration ECROUTE** | | | **Was study treatment followed as expected** **ECTRTCMP** | | |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **[DD-MMM-YYYY]**  |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | | |  | | |  | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **[DD-MMM-YYYY]**  |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | | | |\_\_||\_\_||\_\_| | | | □ mg  □ TABLET | | | | | □ IV  □ PO | | | **□** Yes | | **□** No[[43]](#footnote-43) |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **[DD-MMM-YYYY]**  |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | | |  | | |  | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **[DD-MMM-YYYY]**  |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | | | |\_\_||\_\_||\_\_| | | □ mg  □ TABLET | | | □ IV  □ PO | | | | | **□** Yes | | **□** No[[44]](#footnote-44) | |

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| **Has the dosing regimen changed?** | **Date treatment was changed or interrupted ECENDAT ECENDTC** | **Was the dosing regimen restarted?** | | **Date treatment re-started  ECSTDAT ECSTDTC** | **Reason dose was adjusted or interrupted ECADJ** |
| **□** Dose changed **ECDOSADJ** **□** Interrupted **ECITRPYN □** Discontinued | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **[DD-MMM-YYYY]** | **□**Yes | **□** No | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **[DD-MMM-YYYY]** | **□** Adverse event  **□** Other |

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| **STUDY DRUG ACCOUNTABILITY [DA] DACAT = STUDY MEDICATION** | | | | | | | | |
| *Please complete a separate CRF page for each study drug administered.* Note: This section has been added to capture patient drug accountability to the prescribed study medication regimen at each visit. | | | | | | | | |
| **Study Medication Randomisation Code  DACAT DAREFID** |  | | | | **Name of drug DASCAT** | |  | |
| **STUDY DRUG ACCOUNTABILITY FOR DISPENSED AMOUNT** | | | | | | | | |
| **Was drug accountability performed for dispensed amount? DAPERF** | **□**Yes | | **□** No |  | | | | |
| **Date of completion DADAT DADTC**  **Time of completion DATIM DADTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]** |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | | | **Number of tablets/capsules dispensed at this visit DATEST = Dispensed Amount  DAORRES**  **DAORRESU = TABLET or CAPSULE** | | | | **|\_\_||\_\_||\_\_||\_\_|** |
| **STUDY DRUG ACCOUNTABILITY FOR RETURNED AMOUNT** | | | | | | | | |
| **Was drug accountability performed for returned amount? DAPERF** | | **□**Yes | | **□** No | |  | | |
| **Date of completion DADAT DADTC**  **Time of completion DATIM DADTC** | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]** |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | | | | | | |
| **Number of tablets/capsules returned at this visit DATEST = Returned Amount DAORRES**  **DAORRESU = TABLET or CAPSULE** | | **Expected number of remaining tablets from previous visit DATEST = Expected Remaining Amount DAORRES**  **DAORRESU = TABLET or CAPSULE** | | | | **Number of lost tablets from previous visit DATEST = Lost Amount DAORRES**  **DAORRESU = TABLET or CAPSULE** | | |
| **|\_\_||\_\_||\_\_||\_\_|** | | **|\_\_||\_\_||\_\_||\_\_|** | | | | **|\_\_||\_\_||\_\_||\_\_|** | | |

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| **ADVERSE EVENTS [AE]** *(make multiple copies of this page if necessary)* | | | | | | | | | | | |
| **Has patient experienced any AEs? AEYN [[45]](#footnote-45)** | | | **□** Yes | **□** No | **What is the AE term? AETERM** |  | | | **AE number AESPID** |  | |
| **Date of completion AEDAT AEDTC** | | | | | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]** | | | | | |
| **Start date/time** | | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  [DD-MMM-YYYY] AESTDAT AESTDTC**  **|\_\_|\_\_|:|\_\_|\_\_| [HH:MM] AESTTIM AESTDTC** | | | **End date/time** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY] AEENDAT AEENDTC**  **|\_\_|\_\_|:|\_\_|\_\_| [HH:MM] AEENTIM AEENDTC** | | | **Ongoing? AEONGO**  **AEENRTPT/AEENRF** | | |
| **□** | | |
| **Standard toxicity grade[[46]](#footnote-46) AETOXGRV** | | **□**Grade 1  **AETOXGRV4\_1** | **□** Grade 2  **AETOXGRV4\_2** | | **□** Grade 3  **AETOXGRV4\_3** | **□** Grade 4  **AETOXGRV4\_4** | **□** Grade 5  **AETOXGRV4\_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 | | **If AE related to study treatment, specify IP[[47]](#footnote-47)** | | |
|  | | |
| **Action taken with study treatment AEACN** | | **□** Dose increased | **□** Dose reduced | | **□** Dose not changed | **□** Drug interrupted | **□** Drug withdrawn | | **□** Not applicable | | **□** Unknown |
| **Other action taken[[48]](#footnote-48)**  **AEACNOTH** | | **□**Yes | **□** No | | **Describe other action taken AEACNOTH** | |  | | | | |
| **Is the AE serious[[49]](#footnote-49) AESER** | | **Is this a special interest AE? AESI** | | | **Was a concomitant or additional treatment given due to this adverse event? AECONTRT** | | **Was the AE expected? AEEXP** | | **Was the AE detected at a medically attended visit 39? MAAE** | | |
| **□** Yes | **□** No | **□** Yes | **□** No | | **□** Yes | **□** No | **□** Yes | **□** No | **□** Yes | | **□** No |
| **Give description of the AE** | | | | |  | | | | | | |

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| **SERIOUS ADVERSE EVENTS** [[50]](#footnote-50)– REPEAT AS REQUIRED | | | |
| **What is the AE number** | | **AE number AESPID** |  |
| **SAE Classification** | **□** Fatal[[51]](#footnote-51) **AESDTH**  **□** Life threatening **AESLIFE**  **□** Requires or prolongs hospitalisation **AESHOSP**  **□** Results in permanent or significant disability/incapacity **AESDISAB**  **□** Congenital anomaly/birth defect **AESCONG**  **□** Medically significant **AESMIE**  Describe medically significant condition: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **If hospitalisation/prolonged hospitalisation give admission date**  **HOSTDAT where HOTERM = HOSPITALIZATION**  **HOSTDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **[DD-MMM-YYYY]** |
| **If hospitalisation/prolonged hospitalisation give discharge date**  **HOENDAT where HOTERM = HOSPITALIZATION**  **HOENDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **[DD-MMM-YYYY]** |
| **Give description of the SAE** |  | | |

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| **CONCOMITANT MEDICATION [CM][[52]](#footnote-52)** | | | | | | | | | | |
| **Date of completion CMDAT CMDTC** | | | | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]** | | | | | |
| **Was any medication given? CMYN** [[53]](#footnote-53) | | | | | | | **□** Yes[[54]](#footnote-54) | **□** No | | |
| **Medication**[[55]](#footnote-55)  **CMTRT** | **Dose amount CMDOSAMT** | **Units**  **CMDOSU** | **Frequency**  **CMDOSU** | **Route of administration[[56]](#footnote-56)**  **CMROUTE** | | **Start date  CMSTDAT CMSTDTC**  **Start time CMTIM CMSTDTC** | **End date  CMENDAT CMENDTC**  **End time CMENTIM CMENDTC** | **Ongoing? CMONGO CMENRTPT/CMENRF** | **Indication CMINDC** | |
|  |  | **□** mg  **□** TABLET  **□** mL  **□** Other, specify | **□** QD  **□** BID  **□** TID  **□** Other, specify | **□** PO  **□** IM  **□** IV  **□** TOP  **□** Other, specify | | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY]**  **|\_\_|\_\_|:|\_\_|\_\_| [HH:MM]** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY]**  **|\_\_|\_\_|:|\_\_|\_\_| [HH:MM]** | **□** |  | |
| **Adverse Event Code?** |  |
|  |  | **□** mg  **□** TABLET  **□** mL  **□** Other, specify | **□** QD  **□** BID  **□** TID  **□** Other, specify | **□** PO  **□** IM  **□** IV  **□** TOP  **□** Other, specify | | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**  **[DD-MMM-YYYY]**  **|\_\_|\_\_|:|\_\_|\_\_| [HH:MM]** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|**  **[DD-MMM-YYYY]**  **|\_\_|\_\_|:|\_\_|\_\_| [HH:MM]** | **□** |  | |
| **Adverse Event Code?** |  |

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| **PATIENT VISIT STATUS [DS]** | | | |
| **Visit Day VISIT** |  | **Date of visit VISDAT DSSTDTC** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY]** |
| **Is patient still active in the protocol DSCAT = PROTOCOL MILESTONE** | **□ Yes DSDECOD = OPTED TO CONTINUE INTO NEXT TRIAL ELEMENT** | | **□ No DSDECOD = DECLINED TO CONTINUE INTO NEXT TRIAL ELEMENT**  **If no, complete OVERALL PATIENT DISPOSITION section** |

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| **OVERALL PATIENT DISPOSITION** **[DS] DSCAT** | | |
| **Date of completing this section VISDAT DSDTC** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY]** | |
| **Did the subject complete the study and all follow up visits? DSTERM** | **□ Yes** | **□ No** |
| **DSDECOD = COMPLETED** | **□** Completed | |
| **DSDECOD = COMPLETED** | **□** Discontinuation of treatment but attended all follow up visits | |
| **If no, list reason for non-completion?**  **DSTERM** | **□** Screen Failure | |
| **□** Adverse event/serious adverse event (non-fatal) | |
| **□** Death | |
| **□** Lost to follow-up | |
| **□** Withdrawal by investigator (specify below) | |
| **□** Study terminated by sponsor (specify below) | |
| **□** Withdrawal by subject/guardian (specify below) | |
| **□** Protocol deviation (specify below) | |
| **□** Other (specify below) | |
| **What was the date of the final assessment?**  **DSSTDAT DSSTDTC** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY]** | | |
| **Comment** |  | | |

# **APPENDICES**

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| **APPENDIX A** | | | | | | | | |
| **PHARMACOKINETIC SAMPLING [[57]](#footnote-57)  [PC]** | | | | | | | | |
| **Was PK sampling performed?** **PCYN**[[58]](#footnote-58) | | | | **□** Yes | **□** No | **□** NA**[[59]](#footnote-59)** | | |
| **Date and actual time of sample collection PCDAT PCDTC** | **Date and actual time of study drug intake ECDAT ECDTC** | **Time-point[[60]](#footnote-60)**  **PCTPT** | **Sample type PCSPEC** | **Sample condition**  **PCSPCCND** | **Not done**  **PCSTAT** | **Reason not done PCREASND** | **Result**  **PCORRES** | **Unit PCORRRESU** |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **[DD-MMM-YYYY]**  |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **[DD-MMM-YYYY]**  |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | **PREDOSE** | **□** Serum  **□** Plasma |  | **□** |  |  |  |
| **□** WholeBlood | **□** Dried |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **[DD-MMM-YYYY]**  |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **[DD-MMM-YYYY]**  |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | **D1H6** | **□** Serum  **□** Plasma |  | **□** |  |  |  |
| **□** WholeBlood | **□** Dried |
| |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **[DD-MMM-YYYY]**  |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  **[DD-MMM-YYYY]**  |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | **D7** | **□** Serum  **□** Plasma |  | **□** |  |  |  |
| **□** WholeBlood | **□** Dried |

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| **APPENDIX B** | | | | | | | | | |
| **ECHOCARDIOGRAPH [CV] CVMETHOD = ECHOCARDIOGRAPHY** | | | | | | | | | |
| **Was echocardiography performed for this study? CVYN [[61]](#footnote-61)** | **□** Yes | **□** No | | **If not done, give reason CVREASND** | |  | | | |
| **Date of echocardiograph  CVDAT CVDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]** | | | | | **Time recorded CVTIM CVDTC** | | |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | |
| **Heart rate during the exam** | **VSORRES** | | **beats/min VSORRESU** | |  | | | | |
|  | | | | | **Left** | | | **Right** | |
| **Ventricular diameter in Systole CVTEST = Heart Chamber Volume, EVS** | | | | | **CVORRES** | | **mm CVORRESU** | **CVORRES** | **mm CVORRESU** |
| **Ventricular diameter in Diastole CVTEST = Heart Chamber Volume, EVD** | | | | | **CVORRES** | | **mm CVORRESU** | **CVORRES** | **mm CVORRESU** |
| **Ventricular Ejection fraction CVTEST = Left Ventricular Ejection Fraction, Est or Right Ventricular Ejection Fraction, Est** | | | | | **CVORRES\_LVEF\_C** | | **% CVORRESU** | **CVORRES\_RVEF\_C** | **% CVORRESU** |
| **Fractional Area change CVTEST = Fractional Area Change** | | | | | **CVORRES** | | **% CVORRESU** |  |  |

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| **Overall ECHOCARDIOGRAPH Results CVTEST = interpretation** | **□** Normal | **□** Abnormal | **If abnormal, what abnormalities were found? CVDSIC** |  |
| **If other, please specify** |  |

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| **APPENDIX C** | | | | | | | | | | | | | | | | | | |
| **HOLTER MONITORING [EG] EGMETHOD = HOLTER CONTINUOUS ECG RECORDING** | | | | | | | | | | | | | | | | | | |
| **Was Holter monitoring assessment performed for this study? EGYN** | | | | | | | | | | **□** Yes | | | | **□** No | | | | |
| **Start date and time of Holter monitoring EGDAT EGSTDTC PRSTDTC** | | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]** |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | | | | | | | **End date and time of Holter monitoring EGDAT EGENDTC PRENDTC** | | | | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]** |\_\_|\_\_|:|\_\_|\_\_| **[HH:MM]** | | | | |
| **Number of heartbeats analysed** | | | | | **Duration of Holter analysed** | | | | | **Mean heart rate EGTEST = ECG Mean Heart Rate** | | | | **Minimum heart rate EGTEST = ECG Minimum Heart Rate** | | **Maximum heart rate EGTEST = ECG Maximum Heart Rateff** | | |
| **EGORRES** | | **beats EGORRESU** | | | **EGORRES** | | | **sec EGORRESU** | | **EGORRES** | | **beats/min EGORRESU** | | **EGORRES** | **beats/min EGORRESU** | **EGORRES** | **beats/min EGORRESU** | |
| **Was heart rate variability performed? EGYN** | | | | | | | | | | **□** Yes | | | | **□** No | | **□** NA | | |
| **Standard Deviation of RR intervals** | | | | **SDANN index** | | | | | | **SDNN index** | | | | **rMSSD** | | **pRR50** | | |
|  | **ms** | | |  | | | **ms** | | |  | | **ms** | |  | **ms** |  | **%** | |
| **Power spectral density** | | | | | | |  | | | | | | | | | | | |
| **Supraventricular premature complex EGORRES for EGTEST = Supraventricular Arrhythmias** | | | | | **□**Yes | | | | | | **□**No | | | | | | | |
| **Premature Ventricular complexes EGORRES for EGTEST = Ventricular Arrhythmias** | | | | | **□**Yes (If yes, complete below) | | | | | | **□**No | | | | | | | |
| **□** Premature ventricular complexes multifocal **EGORRES for EGTEST = Ventricular Arrhythmias** | | | | | | | | | **□** Premature ventricular complexes unifocal **EGORRES for EGTEST = Ventricular Arrhythmias** | | | | | **□** Premature ventricular complexes interpolated **EGORRES for EGTEST = Ventricular Arrhythmias** | | | | |
| **Ventricular tachycardia EGORRES** | | | | | **□**Yes (If yes, complete below) | | | | | | **□**No | | | | | | | |
| **□** Ventricular tachycardia, monomorphic **EGORRES for EGTEST = Ventricular Tachyarrhythmias** | | | | | | | | | **□** Ventricular tachycardia, polymorphic **EGORRES for EGTEST = Ventricular Tachyarrhythmias** | | | | | **□** Ventricular tachycardia **EGORRES for EGTEST = Ventricular Tachyarrhythmias** | | | | |
| **Pauses longer than 3 seconds  EGORRES EGTESTCD = RHYNOS** | | | | | **□**Yes | **□**No | | | **Maximum duration of pauses (sec)** | |  | | **Maximum corrected QT interval EGTESTCD = QTCBAG or QTCFAG EGTEST = QTcB Interval Aggregate or QTcF Interval, Aggregate** | | |  | | **msec** |

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| **Overall Holter Results EGINTP EGORRES** | **□** Normal | **□** Abnormal | **If Abnormal, please specify** |  |

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| **APPENDIX D** | | | | |
| **CARDIAC MRI [CV] CVMETHOD = MRI** | | | | |
| **Date of examination CVDAT CVDTC** | |\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| **[DD-MMM-YYYY]** | | | |
| **Delayed myocardial enhancement** | **□** Yes | **□** No | **Segments involved CVLOC** |  |
| **Delayed enhancement distribution** | **□** Subendocardial | **□** Midwall | **□** Subepicardial | **□** Transmural |
| **Ventricular Characterisation** | **Left CVLOC** | | **Right CVLOC** | |
| **Ventricular Ejection fraction  CVTEST = Left Ventricular Ejection Fraction Cal** | **CVORRES** | **CVORRESU** % | **CVORRES** | **CVORRESU** % |
| **Ventricular Ejection Volume  CVTEST = Stroke Volume** | **CVORRES** | **CVORRESU** ml | **CVORRES** | **CVORRESU** ml |
| **End Ventricular Diastole CVTEST = Heart Chamber Volume, EVD** | **CVORRES** | **CVORRESU** ml | **CVORRES** | **CVORRESU** ml |
| **Ventricular Mass Index CVTEST = Left Ventricular Mass Index** | **CVORRES** | **CVORRESU** ml/m² / Corrected for body surface area | **CVORRES** | **CVORRESU** ml/m² / Corrected for body surface area |
| **End Ventricular Systole CVTEST = Heart Chamber Volume, EVS** | **CVORRES** | **CVORRESU** ml | **CVORRES** | **CVORRESU** ml |
| **Ventricular mass CVTESTCD = Left Ventricular Mass, Estimated** | **CVORRES** | **CVORRESU** gr | **CVORRES** | **CVORRESU** gr |
| **Basal anteroseptal wall thickness** | **CVORRES** | **CVORRESU** mm |  | |
| **Basal inferolateral wall thickness** | **CVORRES** | **CVORRESU** mm |  | |

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| **Overall MRI Results CVDESC CVORRES** | **□** Normal | **□** Abnormal | **If Abnormal, please specify** | **□** Cardiomyopathy  **□** Apical aneurysm **CVTEST = Aneurysm Indicator** **□** Other, specify |

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| **APPENDIX E** | | | | | | | | |
| **Date of completing this section VISDAT RPDTC** | | | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY]** | | | | | |
| **DETAILED PREGNANCY STATUS [RP]** ***Only applicable to women of child-bearing potential, as defined in the protocol*** | | | | | | | | |
| **Is the subject pregnant?**  **RPTEST=Pregnant During the Study**  **RPTESTCD=PREGST** | **□** Yes **RPORRES**  **□** No **RPORRES**  **□** UNK[[62]](#footnote-62) **RPORRES**  **□** NA[[63]](#footnote-63) **RPORRES** | | | **Date of last menstrual period (LMP) RPTEST= Last Menstrual Period Start Date RPTESTCD=LMPSTDTC** | | | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  [DD-MMM-YYYY]**  **RPORRES where RPTEST=Last Menstrual Period Start Date** | |
| **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** | **□** Fundal ht[[64]](#footnote-64) | **□** LMP[[65]](#footnote-65) | | | **□** Ultrasound | **□** Other | | **If other, specify**  **RPMETHOTH** |
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| **APPENDIX F** | | | | | | | | |
| **HEPATITIS TESTING** **[MB]** | | | | | | | | |
| **Date of completing this section VISDAT MBDTC** | | | | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY]** | | | | |
| **Was a sample taken for Hepatitis testing?** **MBYN** | **□** Yes | **□** No | **□** NA | | | **Specimen type MBSPEC** | **□** Blood  **□** | |
| **Test name MBTEST** | **Date the sample was collected  MBDAT MBDTC** | | | | **Not done**  **MBSTAT** | **Reason not done  MBREASND** | **Result  MBORRES MBTSTDTL = DETECTION** | |
| **Hepatitis A Virus** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY]** | | | | **□** |  | **□ Negative** | **□ Positive** |
| **Hepatitis B Surface Antigen** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY]** | | | | **□** |  | **□ Negative** | **□ Positive** |
| **Hepatitis B Core Antigen** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY]** | | | | **□** |  | **□ Negative** | **□ Positive** |
| **Hepatitis C Virus** | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY]** | | | | **□** |  | **□ Negative** | **□ Positive** |

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| **APPENDIX G** | | | | | |
| **HIV TESTING** **[MB]** | | | | | |
| **Date of completing this section VISDAT MBDTC** | | **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY]** | | | |
| **Was a sample taken for HIV testing?**  **MBYN where MBTESTCD=HIV** | | **□** Yes | | **□** No | |
| **Date of HIV test**  **MBDAT MBDTC** | **HIV test name**  **MBTEST MBTESTCD** | **Results MBORRES MBTSTDTL = DETECTION** | | **Not done**  **MBSTAT** | **Reason not done**  **MBREASND** |
| **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_| [DD-MMM-YYYY]** |  | **□** Positive If positive, record below | **□** Negative | **□** |  |

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| **APPENDIX H** | | | | | | | | |
| **GENERAL BIOMARKER [MB]  REPEAT AS PER PROTOCOL** | | | | | | | | |
| **Was a diagnostic test performed? MBYN** | **□** Yes | **□** No | **Not done MBSTAT** | **□** | | **Reason not done MBREASND** |  | |
| **Test type MBTEST** |  | | | | | | | |
| **Sample collection date and time  MBDAT MBDTC** | **Sample type MBSPEC** | | **Trade name DIVAL when DIPARM=Trade Name** | **Lot number**  **DIVAL when DIPARM=Lot Name** | **Antigens used** | **Qualitative Results MBORRES MBTSTDTL = DETECTION** | **Quantitative Results MBORRES MBTSTDTL = QUANTIFICATION** | **Quantitative Result Units MBORRES** |
| **|\_\_|\_\_|-|\_\_|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|  [DD-MMM-YYYY]**  **|\_\_|\_\_|:|\_\_|\_\_| [HH:MM]** | **□** Venous blood  **□** Other (describe below) | | **□** \_\_\_ **□** \_\_\_  **□** Other |  |  | **□** Positive  **□** Negative  **□** Intermediate |  |  |

1. Day 0 (D0) is traditionally the day the participant is enrolled in the study and the first dose of medication is administered, referred to as VISIT 1 in SDTM and in the CRF for consistency and to conform to CDISC data standards. [↑](#footnote-ref-1)
2. Recommended follow-up after treatment is 12 months [↑](#footnote-ref-2)
3. Please see user guide if enrolling immunocompromised patients [↑](#footnote-ref-3)
4. Date AND time of Informed Consent is expected in the DM and IC domains, hence the two annotations [↑](#footnote-ref-4)
5. In some countries local privacy law may not allow DOB, in this instance age should be used [↑](#footnote-ref-5)
6. If actual date is unknown use 99 or 999 for place holder for ANY day and month [↑](#footnote-ref-6)
7. 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-7)
8. As recommended by FDA [↑](#footnote-ref-8)
9. The CDASH variable RACEC (Race as Collected) is used in addition to the variable RACE (Race) when more detailed race categorisations 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 v2.3 and the SDTMIG v3.4. [↑](#footnote-ref-9)
10. If surgically sterile, please complete the medical history section [↑](#footnote-ref-10)
11. If using contraceptives, please complete the concomitant medication section [↑](#footnote-ref-11)
12. UNK = unknown [↑](#footnote-ref-12)
13. NA = not applicable [↑](#footnote-ref-13)
14. Males [↑](#footnote-ref-14)
15. Hysterectomy, bilateral salpingectomy, and bilateral oophorectomy [↑](#footnote-ref-15)
16. 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-16)
17. Previous medication duration will be specified in the study protocol [↑](#footnote-ref-17)
18. The period for reporting previous medications will be specified in the protocol [↑](#footnote-ref-18)
19. If concomitant medications were given, enter full trade or generic names [↑](#footnote-ref-19)
20. PO=oral; IV=intravenous; IM=intramuscular; SC=sub-cutaneous; Top=topical; PR=rectal [↑](#footnote-ref-20)
21. For data management, not for inclusion in SDTM [↑](#footnote-ref-21)
22. If vital signs are not available (such as weight and height measurements), check the “not done” box and record reason not done [↑](#footnote-ref-22)
23. The units of measure are an example, the protocol will specify which units the vital signs are to be recorded in [↑](#footnote-ref-23)
24. The method (including site) of recording temperature will be specified in the protocol [↑](#footnote-ref-24)
25. If abnormalities are found at enrolment, record as medical history at the start of the study; if new abnormalities are found on follow up days, record as adverse events [↑](#footnote-ref-25)
26. For data management, not for inclusion in SDTM [↑](#footnote-ref-26)
27. The units of measure are an example, the protocol will specify which unit’s the ECG parameters are to be recorded in [↑](#footnote-ref-27)
28. 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 standard user guide [↑](#footnote-ref-28)
29. The laboratory tests and units shown above are an example, use the laboratory tests and units specified in the protocol [↑](#footnote-ref-29)
30. For data management, not for inclusion in SDTM [↑](#footnote-ref-30)
31. NA = not applicable (not required for this study protocol) [↑](#footnote-ref-31)
32. The units of measure are an example, the protocol will specify which unit’s the lab values are to be recorded in [↑](#footnote-ref-32)
33. Clinical significance will be specified in the protocol [↑](#footnote-ref-33)
34. 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-34)
35. The laboratory tests and units shown above are an example, use the laboratory tests and units specified in the protocol [↑](#footnote-ref-35)
36. NA = not applicable (not required for this study protocol) [↑](#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. 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-39)
40. 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-40)
41. If study drug is interrupted due to rescue treatment, record in concomitant medications module [↑](#footnote-ref-41)
42. 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-42)
43. If no, record details of reasons for any interruptions or changes to the dosing regimen in the table below [↑](#footnote-ref-43)
44. If no, please complete details below [↑](#footnote-ref-44)
45. For data management, not for inclusion in SDTM [↑](#footnote-ref-45)
46. 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-46)
47. IP = investigational product, specify which drug the adverse event is related to if applicable [↑](#footnote-ref-47)
48. If the AE resulted in a treatment administered, please record in the concomitant medication section [↑](#footnote-ref-48)
49. If classified as serious, please complete a SAE CRF

    39 Visits outside of routine study visits as defined in the protocol [↑](#footnote-ref-49)
50. For data management, not for inclusion in SDTM [↑](#footnote-ref-50)
51. If SAE is fatal, date of death will be the same as end date of AE [↑](#footnote-ref-51)
52. The period for reporting concomitant medications will be specified in the protocol [↑](#footnote-ref-52)
53. 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-53)
54. If yes, please complete below [↑](#footnote-ref-54)
55. If concomitant medications were given, enter full trade or generic names [↑](#footnote-ref-55)
56. PO=oral; IV=intravenous; IM=intramuscular; SC=sub-cutaneous; Top=topical; PR=rectal [↑](#footnote-ref-56)
57. 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-57)
58. For data management, not for inclusion in SDTM [↑](#footnote-ref-58)
59. NA = not applicable (not required for this study protocol) [↑](#footnote-ref-59)
60. The specific time-points will be documented in the protocol [↑](#footnote-ref-60)
61. For data management, not for inclusion in SDTM [↑](#footnote-ref-61)
62. UNK = unknown [↑](#footnote-ref-62)
63. NA = not applicable [↑](#footnote-ref-63)
64. Ht = height [↑](#footnote-ref-64)
65. LMP=Last Menstrual Period [↑](#footnote-ref-65)