**Case Report Form**

*STUDY TITLE*

**Chief / Principal Investigator:**

**CRF Version Number:** V / /20

**Sponsor No:**

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**Subject ID Number:**

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**Subject Initials:**

**Sponsor:**

R& I Department

University Hospitals of Leicester NHS Trust

Gwendolen Road

Leicester General Hospital

Leicester

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| Subject ID:   |  |  |  | | --- | --- | --- | |  |  |  | | Subject Initials:   |  |  |  | | --- | --- | --- | |  |  |  | | Visit Date:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | |
| VISIT 1 SCREENING Demographic Data | | |

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| Date of Birth | | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | | | | |
| Ethnicity | | | | | |
| White | White British € | | White Irish € | White Other € | |
| Mixed Race | White & Black  Caribbean € | | White & Black  African € | White & Asian € | Other mixed background € |
| Asian or Asian British | Indian € | | Bangladeshi € | Pakistani € | Other Asian background € |
| Black or Black British | Caribbean € | | African € | Black Other € | |
| Chinese or other ethnicity | Chinese € | | Other € (please specify) | | |

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| Gender | ……………………………………………….. |

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| Subject ID:   |  |  |  | | --- | --- | --- | |  |  |  | | Subject Initials:   |  |  |  | | --- | --- | --- | |  |  |  | | Visit Date:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | |
| VISIT 1 SCREENING Informed Consent Process | | |

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| Informed Consent Process | | | |
| Date & Time subject/relative/witness given/sent Participant Information Sheet | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y |   Date | | |  |  |  |  | | --- | --- | --- | --- | |  |  |  |  | | H | H | M | M |   Time |
| Date & Time subject/relative/witness signed Written Consent Form | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y |   Date | | |  |  |  |  | | --- | --- | --- | --- | |  |  |  |  | | H | H | M | M |   Time |
| Date & Version Number of Participant Information Sheet consented to | Date Version   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y |   v ………… | | |
| Name of person taking Informed Consent | Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| Has a copy of the signed consent form/participant information sheet been given to the subject? | Yes € No € | At time of consent Yes € No €  Posted to subject Yes € No €  Date posted   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y |   If not please explain ……………………………………  ………………………………………………………………….. | |
| Has a copy of the signed consent form/participant information sheet been filed in the medical notes? | Yes € No € | If not please explain  ………………………………….......................................  ……………………………………………………………………….. | |
| Has a written entry detailing the consent process been made in the main body of the medical notes? | Yes € No € | If not please explain ………………………………………………………………………..  ………………………………………………………………………… | |

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| Subject ID:   |  |  |  | | --- | --- | --- | |  |  |  | | Subject Initials:   |  |  |  | | --- | --- | --- | |  |  |  | | Visit Date:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | |
| VISIT 1 SCREENING Inclusion Criteria | | |

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| Date of Assessment | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | |

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| Inclusion Criteria | | | | |
|  | | YES | NO | N/A |
| 1. | *INSERT INCLUSION CRITERIA AS PER PROTOCOL* | € | € | € |
| 2. |  | € | € | € |
| 3. |  | € | € | € |
| 4. |  | € | € | € |
| 5. |  | € | € | € |
| 6. |  | € | € | € |
| 7. |  | € | € | € |
| 8. |  | € | € | € |
| 9. |  | € | € | € |
| 10. |  | € | € | € |
| If any of the above criteria is answered NO, the subject is not eligible for the trial and must not be included in the study. | | | | |

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| Subject ID:   |  |  |  | | --- | --- | --- | |  |  |  | | Subject Initials:   |  |  |  | | --- | --- | --- | |  |  |  | | Visit Date:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | |
| VISIT 1 SCREENING Exclusion Criteria | | |

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| Date of Assessment | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | |

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| Exclusion Criteria | | | |
|  | | YES | NO |
| 1. | *INSERT EXCLUSION CRITERIA AS PER PROTOCOL* | € | € |
| 2. |  | € | € |
| 3. |  | € | € |
| 4. |  | € | € |
| 5. |  | € | € |
| 6. |  | € | € |
| 7. |  | € | € |
| 8. |  | € | € |
| 10. |  | € | € |
| If any of the above criteria is answered YES, the subject is not eligible for the trial and must not be included in the study. | | | |

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| Subject ID:   |  |  |  | | --- | --- | --- | |  |  |  | | Subject Initials:   |  |  |  | | --- | --- | --- | |  |  |  | | Visit Date:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | |
| VISIT 1 SCREENING Medical History | | |

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| Medical History | | | | |
| Has the subject had any relevant medical history? | | No € Yes € complete below  If not please explain …………………………….  …………………………………………………………… | | |
| Date of Assessment | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | | | | |
| Condition/Illness / Surgical Procedure | Start Date  (DD/MM/YYYY) | | Stop Date  (DD/MM/YYYY) | OR tick if on going at screening visit |
|  | \_\_\_\_\_/ \_\_\_\_\_\_/\_\_\_\_\_\_\_\_ | | \_\_\_\_\_\_/ \_\_\_\_\_\_/\_\_\_\_\_\_\_\_ | € |
|  | \_\_\_\_\_\_/ \_\_\_\_\_\_/\_\_\_\_\_\_\_\_ | | \_\_\_\_\_\_/ \_\_\_\_\_\_/\_\_\_\_\_\_\_\_ | € |
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|  | \_\_\_\_\_\_/ \_\_\_\_\_\_/\_\_\_\_\_\_\_\_ | | \_\_\_\_\_\_/ \_\_\_\_\_\_/\_\_\_\_\_\_\_\_ | € |
|  | \_\_\_\_\_\_/ \_\_\_\_\_\_/\_\_\_\_\_\_\_\_ | | \_\_\_\_\_\_/ \_\_\_\_\_\_/\_\_\_\_\_\_\_\_ | € |
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| Subject ID:   |  |  |  | | --- | --- | --- | |  |  |  | | Subject Initials:   |  |  |  | | --- | --- | --- | |  |  |  | | Visit Date:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | |
| VISIT 1 SCREENING Physical Examination | | |

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| Physical Examination | | | | | | |
| Was a physical examination performed? | | | | | No € Yes € complete below  If not please explain …………………………………………..  …………………………………………………………………………. | |
| Date of examination | | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | | | | | |
| System | \*Abnormal | | Normal | Not Done | | if ABNORMAL, please provide brief description and record if clinically significant or not (CS/NCS) | |
| General Appearance | € | | € | € | |  | |
| Skin | € | | € | € | |  | |
| Eyes, Ears, Nose & Throat | € | | € | € | |  | |
| Head, Neck & Thyroid | € | | € | € | |  | |
| Cardiovascular | € | | € | € | |  | |
| Respiratory | € | | € | € | |  | |
| Abdomen | € | | € | € | |  | |
| Extremities | € | | € | € | |  | |
| Genitalia | € | | € | € | |  | |
| Anorectal | € | | € | € | |  | |
| Lymph Nodes | € | | € | € | |  | |
| Muscular-Skeletal | € | | € | € | |  | |
| Neurological | € | | € | € | |  | |
| Others (please specify) | € | | € | € | |  | |

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| Subject ID:   |  |  |  | | --- | --- | --- | |  |  |  | | Subject Initials:   |  |  |  | | --- | --- | --- | |  |  |  | | Visit Date:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | |
| VISIT 1 SCREENING Vital Signs & ECG | | |

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| Vital Signs & ECG | | | | | | |
| Were vital signs performed? | | | | | No € Yes € complete below  If not please explain …………………………………………..  …………………………………………………………………………. | |
| Date of Vital Signs | | | | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | | | |
| Time of Vital Signs | | | | |  |  |  |  | | --- | --- | --- | --- | |  |  |  |  | | H | H | M | M | | | |
| Blood Pressure supine/standing/seated / mmHG | | | | | | |
| Pulse beats/min | | | | | | |
| Weight . kg Height . m | | | | | | |
| Temperature . °c | | | | | | |
| Was an ECG performed? No € Yes € complete below If not please explain ……………….………………………………………………………………………………………………………………………………………………. | | | | | | |
| Date ECG performed | | | | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | | | |
| Time ECG performed | | | | |  |  |  |  | | --- | --- | --- | --- | |  |  |  |  | | H | H | M | M | | | |
| The ECG is | | € Within normal limits  € Abnormal, NOT clinically significant  € Abnormal, Clinically Significant, please specify: …………………………………………..  ………………………………………………………………………………………………………………………... | | | | |
| Subject ID:   |  |  |  | | --- | --- | --- | |  |  |  | | | Subject Initials:   |  |  |  | | --- | --- | --- | |  |  |  | | | | Visit Date:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | |
| VISIT 1 (SCREENING) Haematology | | | | | |

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| Haematology | | | | | |
| Clinical Haematology Laboratory tests performed? | | | | No € Yes € complete below  If not please explain …………………………………………..  …………………………………………………………………………. | |
| Date of Sample | | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | | | | |
| Time of Sample | | |  |  |  |  | | --- | --- | --- | --- | |  |  |  |  | | H | H | M | M | | | | |
|  | | | | | |
| Haematology | Value | | Unit | | If indicated as out of normal range on report, please state if clinically significant |
| WBC |  | |  | | No € Yes € |
| RBC |  | |  | | No € Yes € |
| Hb |  | |  | | No € Yes € |
| HCT |  | |  | | No € Yes € |
| MCV |  | |  | | No € Yes € |
| MCH |  | |  | | No € Yes € |
| PLT |  | |  | | No € Yes € |
| NEUTROPHILS |  | |  | | No € Yes € |
| LYMPHOCYTES |  | |  | | No € Yes € |
| MONOCYTES |  | |  | | No € Yes € |
| EOSINOPHILS |  | |  | | No € Yes € |
| BASOPHILS |  | |  | | No € Yes € |
| RETICULOCYTES |  | |  | | No € Yes € |

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| VISIT 1 SCREENING Biochemistry |

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| Biochemistry | | | | | |
| Clinical Biochemistry Laboratory tests performed? | | | | No € Yes € complete below  If not please explain …………………………………………..  …………………………………………………………………………. | |
| Date of Sample | | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | | | | |
| Time of Sample | | |  |  |  |  | | --- | --- | --- | --- | |  |  |  |  | | H | H | M | M | | | | |
|  | | | | | |
| Biochemistry | Value | | Unit | | If indicated as out of normal range on report, please state if clinically significant |
| SODIUM |  | |  | | No € Yes € |
| POTASSIUM |  | |  | | No € Yes € |
| CHLORIDE |  | |  | | No € Yes € |
| BICARBONATE |  | |  | | No € Yes € |
| UREA |  | |  | | No € Yes € |
| CREATININE |  | |  | | No € Yes € |
| TOTAL PROTEIN |  | |  | | No € Yes € |
| TOTAL BILIRUBIN |  | |  | | No € Yes € |
| ALBUMIN |  | |  | | No € Yes € |
| ALK PHOS |  | |  | | No € Yes € |
| ALT |  | |  | | No € Yes € |
| AST |  | |  | | No € Yes € |
| CALCIUM |  | |  | | No € Yes € |

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| *INSERT ASSESSMENT* | | | | | |
| Clinical *INSERT ASSESSMENT* Laboratory tests performed? | | | | No € Yes € complete below  If not please explain …………………………………………..  …………………………………………………………………………. | |
| Date of Sample | | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | | | | |
| Time of Sample | | |  |  |  |  | | --- | --- | --- | --- | |  |  |  |  | | H | H | M | M | | | | |
|  | | | | | |
| *INVESTIGATOR TO INSERT OTHER ASSESSMENT* | Value | | Unit | | If indicated as out of normal range on report, please state if clinically significant |
|  |  | |  | | No € Yes € |
|  |  | |  | | No € Yes € |
|  |  | |  | | No € Yes € |
|  |  | |  | | No € Yes € |
|  |  | |  | | No € Yes € |
|  |  | |  | | No € Yes € |
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| Subject ID:   |  |  |  | | --- | --- | --- | |  |  |  | | Subject Initials:   |  |  |  | | --- | --- | --- | |  |  |  | | Visit Date:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | |
| VISIT 1 SCREENING Screening Concomitant Medication | | |

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| Concomitant Medications | | | | | | | | | | |
| Date of Assessment | | | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | | | | | | | | |
| Is the subject taking any concomitant medications? | | | | | |  | | No € Yes € complete below | | |
| Medication | Reason for use | Dose & Units | | Frequency | Route | | Start Date  (DD/MM/YYYY) | | Stop Date  (DD/MM/YYYY) | OR tick if on going at time of screening visit |
| 1. |  |  | |  |  | | / / | | / / | € |
| 2. |  |  | |  |  | | / / | | / / | € |
| 3. |  |  | |  |  | | / / | | / / | € |
| 4. |  |  | |  |  | | / / | | / / | € |
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| 6. |  |  | |  |  | | / / | | / / | € |
| 7. |  |  | |  |  | | / / | | / / | € |
| 8. |  |  | |  |  | | / / | | / / | € |
| 9. |  |  | |  |  | | / / | | / / | € |
| 10. |  |  | |  |  | | / / | | / / | € |

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| Subject ID:   |  |  |  | | --- | --- | --- | |  |  |  | | Subject Initials:   |  |  |  | | --- | --- | --- | |  |  |  | | Visit Date:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | |
| VISIT 1 SCREENING Smoking / Alcohol | | |

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| Date of Assessment | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | |

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| Smoking / Alcohol | | |
| Has the subject ever smoked? | | No € Yes € complete below |
| € Current Smoker | Subject’s average daily use:  Number smoked per day | |
| € Former Smoker | Smoked for months / years   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y |   Date when smoking ceased | |
| Participants alcohol consumption  Wine units per week / month  Beer units per week / month  Spirits units per week / month | | |

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| Subject ID:   |  |  |  | | --- | --- | --- | |  |  |  | | Subject Initials:   |  |  |  | | --- | --- | --- | |  |  |  | | Visit Date:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | |
| VISIT 1 SCREENING Subject Eligibility Review | | |

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| Date of Assessment | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | |

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| Participant Eligibility Review | | | |
|  |  | YES | NO |
| 1. | Does the subject satisfy the inclusion/exclusion criteria? | € | € |
| 2. | Have the medical history and concomitant medication pages been completed? | € | € |
| 3. | Is the subject still willing to proceed in the trial? | € | € |

|  |  |
| --- | --- |
| Subject’s eligibility Investigator sign-off | |
| Is the subject eligible to take part in the Clinical Trial?  Principal Investigator’s (or delegated individual\*) Signature:  Date:  \_\_\_ \_\_\_ / \_\_\_ \_\_\_/ \_\_\_ \_\_\_ \_\_\_ (DD/MM/YYYY)  Investigator’s Name:  \*Must be reflected in the Delegation of Authority Log | € YES  € NO Please give reason below |
| Reason(s) for screen failure | |
| 1. | |
| 2. | |
| 3. | |

|  |  |
| --- | --- |
| Subject Randomisation/Enrolment | |
| Subject Study Number Allocated | Subject ID  \_\_\_\_\_ \_\_\_\_\_ \_\_\_\_\_\_ |
| Date of Randomisation/Enrolment | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| Subject ID:   |  |  |  | | --- | --- | --- | |  |  |  | | Subject Initials:   |  |  |  | | --- | --- | --- | |  |  |  | | Visit Date:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | |
| VISIT 1 SCREENING Investigational Medicinal Product | | |

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| Date of Assessment | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | |

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| Investigational Medicinal Product | | | | | |
|  |  | | YES | NO | |
| 1. | Has the subject been issued with the Trial Medication as per protocol? | | € | €  If NOT explain  ……………………………………………………………… | |
| 2. | Has the subject received instruction / guidance on how to take the Trial Medication? | | € | €  If NOT explain | |
|  | | | | | |
| Randomisation | | | | | |
| Subject randomised to: | | Arm *INSERT AS PER PROTOCOL*  € | | | Arm *INSERT AS PER PROTOCOL*  € |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| Subject ID:   |  |  |  | | --- | --- | --- | |  |  |  | | Subject Initials:   |  |  |  | | --- | --- | --- | |  |  |  | | Visit Date:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | |
| VISIT *INSERT VISIT NAME OR NUMBER AS PER PROTOCOL* Checklist | | |

|  |  |  |  |
| --- | --- | --- | --- |
| Visit Checklist | | | |
|  | | YES | NO |
| 1. | Did the subject experience any new or changes to existing adverse events since the screening visit/previous visit? If YES, please complete adverse event page  *(If an AE is marked as serious this must be reported to the Sponsor within 24 hours of the research team being made aware of the event, utilising the Sponsor SAE form as per Sponsor SOP S-1009)* | € | € |
| 2. | Have there been any changes to existing medication, or the subject has taken any new medication since the screening visit/previous visit? If YES, please complete concomitant medication page | € | € |
| 3. | *INVESTIGATOR TO ADD OTHER REQUIRED ASSESSMENTS AS PER PROTOCOL* | € | € |
| 4. |  | € | € |

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| Subject ID:   |  |  |  | | --- | --- | --- | |  |  |  | | Subject Initials:   |  |  |  | | --- | --- | --- | |  |  |  | | Visit Date:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | |
| VISIT *INSERT VISIT NAME OR NUMBER AS PER PROTOCOL* Physical Examination | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Physical Examination | | | | | | |
| Was a physical examination performed? | | | | | No € Yes € complete below  If not please explain …………………………………………..  …………………………………………………………………………. | |
| Date of examination | | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | | | | | |
| System | \*Abnormal | | Normal | Not Done | | \*if noted ABNORMAL, please provide brief description and comment if clinically significant or not (CS/NCS) | |
| General Appearance | € | | € | € | |  | |
| Skin | € | | € | € | |  | |
| Eyes, Ears, Nose & Throat | € | | € | € | |  | |
| Head, Neck & Thyroid | € | | € | € | |  | |
| Cardiovascular | € | | € | € | |  | |
| Respiratory | € | | € | € | |  | |
| Abdomen | € | | € | € | |  | |
| Extremities | € | | € | € | |  | |
| Genitalia | € | | € | € | |  | |
| Anorectal | € | | € | € | |  | |
| Lymph Nodes | € | | € | € | |  | |
| Muscular-Skeletal | € | | € | € | |  | |
| Neurological | € | | € | € | |  | |
| Others (please specify) | € | | € | € | |  | |

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| Subject ID:   |  |  |  | | --- | --- | --- | |  |  |  | | Subject Initials:   |  |  |  | | --- | --- | --- | |  |  |  | | Visit Date:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | |
| VISIT *INSERT VISIT NAME OR NUMBER AS PER PROTOCOL* Vital Signs | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Vital Signs & ECG | | | | | | |
| Were vital signs performed? | | | | | No € Yes € complete below  If not please explain …………………………………………..  …………………………………………………………………………. | |
| Date of Vital Signs | | | | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | | | |
| Time of Vital Signs | | | | |  |  |  |  | | --- | --- | --- | --- | |  |  |  |  | | H | H | M | M | | | |
| Blood Pressure supine/standing/seated / mmHG | | | | | | |
| Pulse beats/min | | | | | | |
| Weight . kg Height . m | | | | | | |
| Temperature . °c | | | | | | |
| Was an ECG performed? No € Yes € complete below If not please explain ……………….………………………………………………………………………………………………………………………………………………. | | | | | | |
| Date ECG performed | | | | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | | | |
| Time ECG performed | | | | |  |  |  |  | | --- | --- | --- | --- | |  |  |  |  | | H | H | M | M | | | |
| The ECG is | | € Within normal limits  € Abnormal, NOT clinically significant  € Abnormal, Clinically Significant, please specify: ……………………………………………  ……………………………………………………………………………………………………………………….. | | | | |
| Subject ID:   |  |  |  | | --- | --- | --- | |  |  |  | | | Subject Initials:   |  |  |  | | --- | --- | --- | |  |  |  | | | | Visit Date:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | |
| VISIT *INSERT VISIT NAME OR NUMBER AS PER PROTOCOL* Haematology | | | | | |

|  |  |  |  |  |  |
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| Haematology | | | | | |
| Clinical Haematology Laboratory tests performed? | | | | No € Yes € complete below  If not please explain …………………………………………..  …………………………………………………………………………. | |
| Date of Sample | | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | | | | |
| Time of Sample | | |  |  |  |  | | --- | --- | --- | --- | |  |  |  |  | | H | H | M | M | | | | |
|  | | | | | |
| Haematology | Value | | Unit | | If indicated as out of normal range on report, please state if clinically significant |
| WBC |  | |  | | No € Yes € |
| RBC |  | |  | | No € Yes € |
| Hb |  | |  | | No € Yes € |
| HCT |  | |  | | No € Yes € |
| MCV |  | |  | | No € Yes € |
| MCH |  | |  | | No € Yes € |
| PLT |  | |  | | No € Yes € |
| NEUTROPHILS |  | |  | | No € Yes € |
| LYMPHOCYTES |  | |  | | No € Yes € |
| MONOCYTES |  | |  | | No € Yes € |
| EOSINOPHILS |  | |  | | No € Yes € |
| BASOPHILS |  | |  | | No € Yes € |
| RETICULOCYTES |  | |  | | No € Yes € |

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| Biochemistry | | | | | |
| Clinical Biochemistry Laboratory tests performed? | | | | No € Yes € complete below  If not please explain …………………………………………..  …………………………………………………………………………. | |
| Date of Sample | | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | | | | |
| Time of Sample | | |  |  |  |  | | --- | --- | --- | --- | |  |  |  |  | | H | H | M | M | | | | |
|  | | | | | |
| Biochemistry | Value | | Unit | | If indicated as out of normal range on report, please state if clinically significant |
| SODIUM |  | |  | | No € Yes € |
| POTASSIUM |  | |  | | No € Yes € |
| CHLORIDE |  | |  | | No € Yes € |
| BICARBONATE |  | |  | | No € Yes € |
| UREA |  | |  | | No € Yes € |
| CREATININE |  | |  | | No € Yes € |
| TOTAL PROTEIN |  | |  | | No € Yes € |
| TOTAL BILIRUBIN |  | |  | | No € Yes € |
| ALBUMIN |  | |  | | No € Yes € |
| ALK PHOS |  | |  | | No € Yes € |
| ALT |  | |  | | No € Yes € |
| AST |  | |  | | No € Yes € |
| CALCIUM |  | |  | | No € Yes € |

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| Subject ID:   |  |  |  | | --- | --- | --- | |  |  |  | | Subject Initials:   |  |  |  | | --- | --- | --- | |  |  |  | | Visit Date:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | |
| VISIT *INSERT VISIT NAME OR NUMBER AS PER PROTOCOL* Trial Medication Accountability | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| *INSERT ASSESSMENT* | | | | | |
| Clinical *INSERT ASSESSMENT* Laboratory tests performed? | | | | No € Yes € complete below  If not please explain …………………………………………..  …………………………………………………………………………. | |
| Date of Sample | | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | | | | |
| Time of Sample | | |  |  |  |  | | --- | --- | --- | --- | |  |  |  |  | | H | H | M | M | | | | |
|  | | | | | |
| *INSERT ASSESSMENT* | Value | | Unit | | If indicated as out of normal range on report, please state if clinically significant |
|  |  | |  | | No € Yes € |
|  |  | |  | | No € Yes € |
|  |  | |  | | No € Yes € |
|  |  | |  | | No € Yes € |
|  |  | |  | | No € Yes € |
|  |  | |  | | No € Yes € |
|  |  | |  | | No € Yes € |
|  |  | |  | | No € Yes € |
|  |  | |  | | No € Yes € |
|  |  | |  | | No € Yes € |
|  |  | |  | | No € Yes € |

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| Subject ID:   |  |  |  | | --- | --- | --- | |  |  |  | | Subject Initials:   |  |  |  | | --- | --- | --- | |  |  |  | | Visit Date:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | |
| VISIT *INSERT VISIT NAME OR NUMBER AS PER PROTOCOL* Trial Medication Accountability | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Investigational Medicinal Product | | | | | |
|  |  | | YES | NO | |
| 1. | Has the subject been issued with the Trial Medication as per protocol? | | € | €  If NOT explain  ……………………………………………………………… | |
| 2. | Has the subject received instruction / guidance on how to take the Trial Medication? | | € | €  If NOT explain | |
|  | | | | | |
| Trial Medication Returns | | | | | |
|  | Trial Medication Name | Quantity Returned | | | Date of Return  DD/MM/YYYY |
| 1. |  |  | | | / / |
| 2. |  |  | | | / / |
| 3. |  |  | | | / / |
| 4. |  |  | | | / / |

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| Subject ID:   |  |  |  | | --- | --- | --- | |  |  |  | | | Subject Initials:   |  |  |  | | --- | --- | --- | |  |  |  | | | Visit Date:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | | |
| END OF TRIAL | | | | | |
| Date of trial completion/withdrawal | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | | | | | |
|  | | | | | |
| Date last trial medication given | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | D | D | M | M | Y | Y | | | | | |
|  | | | | | |
| Trial Participation Outcome | | | YES | | NO |
| Completed trial | | | € | | € |
| Withdrawn from trial (complete withdrawal form below) | | | € | | € |
|  | | | | | |
| Trial Withdrawal Form | | | | | |
| Reason for Withdrawal | | | YES | | NO |
| Lost to follow up | | | € | | € |
| Non-compliance | | | € | | € |
| Concomitant medication | | | € | | € |
| Medical contraindication | | | € | | € |
| Consent withdrawn | | | € | | € |
| AE/SAE/SUSAR (complete SAE form) | | | € | | € |
| Death (complete SAE form) | | | € | | € |
| Other (explain) ………………………………………………..  ……………………………………………………………………….. | | | € | | € |

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| --- |
| Chief/ Principal Investigator Sign Off |
| I ……………………………………………………(name)confirm that I have reviewed the case report form and confirm that to the best of my knowledge, the information contained within is accurate and complete.  Signature …………………………………………………………………………. Date / / DD/MM/YYYY |

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| Concomitant Medications Form | | | | Subject ID:   |  |  |  | | --- | --- | --- | |  |  |  | | | | | |  |  |  | | --- | --- | --- | |  |  |  |   Subject Initials: | | | |
| Have there been any changes to existing medication, or the subject has taken any new medication since the screening visit? NO € YES € (record below) | | | | | | | | | | | |
|  | **Medication name** (Generic term preferred) | **Reason for use** | **Start Date**  (DD/MM/YYYY) | | **End Date**  (DD/MM/YYYY) | **Dose** | **Unit** | | **Route** | **Frequency** | **Continuing at the end of the study?** |
| 1. |  |  | **/ /** | | **/ /** |  |  | |  |  | € |
| 2. |  |  | **/ /** | | **/ /** |  |  | |  |  | € |
| 3. |  |  | **/ /** | | **/ /** |  |  | |  |  | € |
| 4. |  |  | **/ /** | | **/ /** |  |  | |  |  | € |
| 5. |  |  | **/ /** | | **/ /** |  |  | |  |  | € |
| 6. |  |  | **/ /** | | **/ /** |  |  | |  |  | € |
| 7. |  |  | **/ /** | | **/ /** |  |  | |  |  | € |
| 8. |  |  | **/ /** | | **/ /** |  |  | |  |  | € |
| 9. |  |  | **/ /** | | **/ /** |  |  | |  |  | € |
| 10. |  |  | **/ /** | | **/ /** |  |  | |  |  | € |
| 11. |  |  | **/ /** | | **/ /** |  |  | |  |  | € |
| 12. |  |  | **/ /** | | **/ /** |  |  | |  |  | € |

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| Adverse Events Form | | | |  |  |  | | --- | --- | --- | |  |  |  |   Subject ID | | | | |  |  |  | | --- | --- | --- | |  |  |  |   Subject Initials: | | | |
|  | Adverse Event Description | **Start Date**  (DD/MMM/YYYY) | | **End Date**  (DD/MMM/YYYY) | **In case of SAE- Please specify the criteria**  1= Death  2 = Life threatening  3 = Hospitalisation  4 = Medically significant  5 = Congenital abnormality/birth defect | **Severity**  1= Mild  2 = Moderate  3= Severe | | **Causality assessment**  1= Certain  2 = Probable/  Likely  3 = Possible  Unlikely  4 = Conditional/  Unclassified  5 = Assessable/  Unclassifiable | **Action taken**  **with trial treatment**  1=Dose modification  2=Discontinuation of the IMP  3= Not applicable  4 = Treatment continued without change | **Outcome**  1=Resolved  2=Resolved with sequelae  3= Ongoing  4= Fatal  5= Unknown |
| 1. |  | **/ /** | | **/ /** |  |  | |  |  |  |
| 2. |  | **/ /** | | **/ /** |  |  | |  |  |  |
| 3. |  | **/ /** | | **/ /** |  |  | |  |  |  |
| 4. |  | **/ /** | | **/ /** |  |  | |  |  |  |
| 5. |  | **/ /** | | **/ /** |  |  | |  |  |  |
| 6. |  | **/ /** | | **/ /** |  |  | |  |  |  |
| 7. |  | **/ /** | | **/ /** |  |  | |  |  |  |
| 8. |  | **/ /** | | **/ /** |  |  | |  |  |  |
| 9. |  | **/ /** | | **/ /** |  |  | |  |  |  |
| 10. |  | **/ /** | | **/ /** |  |  | |  |  |  |
| 11. |  | **/ /** | | **/ /** |  |  | |  |  |  |
| 12. |  | **/ /** | | **/ /** |  |  | |  |  |  |

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| --- | --- | --- | --- |
| Receipt of Device | Use of Device | Disposition (Return/Repair/Destruction) | |
| \*Status  RET = Returned  DES = Destroyed  REP = Repaired  LOS = Lost  OTH = Other(must comment) | \*\* Reasons  1 = Subject completed study  2 = Subject Withdrew  3 = Lost to follow-up  4 = Expired  5 = Device damaged. not functioning or recalled |

**Investigational Medical Device Accountability Log**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Date Rec’d | Initials of receiver | Lot/serial or Model Number | Device Type/Batch | Date Used | Initials of device  dispenser | Subject ID | Status\* | Date | Initials | Number  of units | Reason\*\* | Comments |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
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**Adverse**

**Event/Device Effect Record**

**For UHL Sponsored Medical Device**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Adverse event/ Device Effect Description** | **Start Date**  **(DD/MMM/YYYY)** | **End Date**  **(DD/MMM/YYYY)** | **Is the AE/ADE and SAE/SADE**  **1= Yes**  **2= No** | **If Event is a SAE/ SADE- Please specify the criteria**  **1= Death**  **2 = Life threatening**  **3 = Hospitalisation**  **4 = Medically significant**  **5 = Congenital abnormality/birth defect** | **Causality assessment**  **1=Related**  **2=Not Related** | **Expectedness**  **Assessment**  **1=Expected**  **2=Unexpected** | **1=Resolved**  **2=Resolved with sequelae**  **3= Ongoing**  **4= Fatal**  **5= Unknown** |
| 1 |  | **--/--/----** | **--/--/----** |  |  |  |  |  |
| 2 |  | **--/--/----** | **--/--/----** |  |  |  |  |  |
| 3 |  | **--/--/----** | **--/--/----** |  |  |  |  |  |