|  |  |  |
| --- | --- | --- |
| **PARTICIPANT ID** | **SITE** | **PRINCIPAL INVESTIGATOR** |
|  |  |  |

|  |  |
| --- | --- |
| **Visit number** |  |
| **Date of Visit (DD/MM/YYYY)** |  |
| **Does the subject continue to meet Inclusion criteria? If no, please give details.** | YES NO |
| **Does the subject continue to not meet Exclusion criteria? If no, please give details.** | YES NO |
| **Does the participant continue ongoing consent?** | YES NO |

**CONCOMITANT MEDICATION**

|  |  |
| --- | --- |
| **Are there any changes to concomitant medications?** |  YES NO**If Yes, please report on the concomitant medications worksheet.** |

**ADVERSE EVENTS**

|  |  |
| --- | --- |
| **Are there any adverse events to report?** |  YES NO**If Yes, please report on the AE worksheet.** |

**VITAL SIGNS**

|  |  |  |
| --- | --- | --- |
| **Has the subject sat for at least 5 minutes?** |  **Yes - No**  | **INITIAL** |
| **On what date and time were the measurements performed?** | **DATE** | **TIME** |  |
| **Height (cm)** |  |  |
| **Weight (kg)** |  |  |
| **Temperature**  |  **OC** |  |
| **Systolic Blood Pressure** |  **mmHg** |  |
| **Diastolic Blood Pressure** |  **mmHg** |  |
| **Pulse Rate** |  **beats/min** |  |
| **Respiratory Rate** |  **breaths/min** |  |
| **Oxygen Saturations** |  **%** |  |

**Page completed by:**

|  |  |  |
| --- | --- | --- |
| **Name** | **Signature** | **Date** |
|  |  |  |

**PHYSICAL EXAMINATION**

|  |  |
| --- | --- |
| **What was the physical examination date? (dd-mon-yyyy)** |   |
| **Body system examined** | **Normal** | **Abnormal** | **If abnormal what were findings? Clinically significant?** |
| GENERAL APPEARANCE |  |  |  |
| SKIN |  |  |  |
| NECK INCLUDING THYROID |  |  |  |
| HEENT |  |  |  |
| LUNGS |  |  |  |
| HEART |  |  |  |
| ABDOMEN |  |  |  |
| BACK |  |  |  |
| LYMPH NODES |  |  |  |
| EXTREMITIES |  |  |  |
| VASCULAR |  |  |  |
| NEUROLOGICAL |  |  |  |
| GENITOURINARY |  |  |  |
| OTHER (Specify) |  |  |  |

**Page Completed by Doctor:**

|  |  |  |
| --- | --- | --- |
| **Name** | **Signature** | **Date** |
|  |  |  |

**SAMPLES**

|  |  |  |
| --- | --- | --- |
| **Time of collection** | **DATE** | **TIME** |
| **Location of draw**  |  |
| **Chemistry** |  YES NO  |
| **Haematology** |  YES NO  |
| **Pregnancy test** |  YES NO N/A  | **Kit Manufacturer** |  |
| **Kit Lot Number** |  | **Kit Expiry** |  |
| **Urinalysis**  |  YES NO  |
| **Time of processing** |  | **Time of freezing** |  |
| **Ascension number** |  | **Waybill number** |  |

 **IMP RETURNS AND DISPENSING**

|  |  |
| --- | --- |
| **IMP RETURNED** |  YES NO  |
|  | **KIT NUMBER** | **RETURNED** | **EXPIRY** |
| 1 |  |  |  |
| 2 |  |  |  |
| 3 |  |  |  |
| **IMP DISPENSED** |  YES NO |
|  | **KIT NUMBER** | **DISPENSED** | **EXPIRY** |
| 1 |  |  |  |
| 2 |  |  |  |
| 3 |  |  |  |

**Page completed by Nurse:**

|  |  |  |
| --- | --- | --- |
| **Name** | **Signature** | **Date** |
|  |  |  |

|  |
| --- |
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