This Example CRF can be used as a starting point for designing a study specific CRF. The CRF should include all data which the protocol states will be collected.

|  |  |
| --- | --- |
| CASE REPORT FORM | |
| STUDY TITLE | |
| Insert brief title | |
| Study reference number | insert |

|  |  |
| --- | --- |
| CLINICAL TRIAL SITE/UNIT: |  |
| PRINCIPAL INVESTIGATOR: |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | |
| Subject Initials: |  |  | |  | |
|  | | | | | | | |
| Subject Randomisation Number: |  | |  | |  | |  |
|  | | | | | | | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ***I am confident that the information supplied in this case record form is complete and accurate data. I confirm that the study was conducted in accordance with the protocol and any protocol amendments and that written informed consent was obtained prior to the study.*** | | | | | | | | | | | |
| Investigator’s Signature: |  | | | | | | | | | |  |
|  | | | | | | | | | | | |
| Date of signature: | |  |  |  |  |  |  |  |  |  |  |
|  | | D | d | m | m | m | y | y | y | y |  |
|  | | | | | | | | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Inclusion Criteria | | Yes |  | No\* |
| 1 | Is the subject a healthy male aged between 18 and 60 years? |  |  |  |
|  |  |  |  |  |
| 2 | Has the subject willingly given written informed consent? |  |  |  |
|  |  |  |  |  |
| 3 |  |  |  |  |
|  |  |  |  |  |
| 4 |  |  |  |  |
|  |  |  |  |  |
| 5 |  |  |  |  |
| \*If any inclusion criteria are ticked no then the patient is not eligible for the study. | |  |  |  |
| **Exclusion Criteria** | | Yes\* |  | No |
| 1 |  |  |  |  |
|  |  |  |  |
|  |  |  |  |  |
| 2 |  |  |  |  |
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| 8 |  |  |  |  |
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| 9 |  |  |  |  |
| \* If any exclusion criteria are ticked yes then the patient is not eligible for the study. | |  |  |  |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Signature: |  | Date: |  |  |  |  |  |  |  |  |  |
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**VISIT 1 (SCREENING)**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**DD MMM YYYY**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| INFORMED CONSENT | | | | | |
| Please note: written informed consent must be given before any study specific procedures take place or any current therapy is discontinued for the purposes of participation in this study. | | | | | |
|  | | | | | |
| Has the subject freely given written informed consent? | Yes |  | No |  |  |
|  | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| DEMOGRAPHIC DATA | | | | | | | | | | | | |
| Age (yrs): |  |  |  | Sex: | | Female | |  | Male | |  |  |
|  | | | | | | | | | | | | |
| Height (m): | | | | |  |  |  |  |  |  |  |  |
|  | | | | | | | | | | | | |
| Weight (Kg): | | | | |  |  |  |  |  |  |  |  |
|  | | | | | | | | | | | | |
| Body Mass Index (BMI = Wt (kg)/H2 (M): | | | | |  |  |  |  |  |  |  |  |
|  | | | | | | | | | | | | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| SMOKING HABITS | | | | | | | | | |
| Does the subject smoke or use tobacco products? | | | | | \*Yes |  | No |  |  |
|  | | | | | | | | | |
| **\*** how many cigarettes per day? | |  |  |  | | | | | |
|  | | | | | | | | | |
| Other, specify | -------------------------------------------------------------- | | | | | | | | |
|  |  | | | | | | | | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ALCOHOL CONSUMPTION | | | | | | | | | | | |
| Does the subject consume alcohol? | | |  |  | Yes | |  | No | |  |  |
|  | | | | | | | | | | | |
| If yes, how many units per week? |  |  |  |  |  |  |  |  |  |  |  |
|  | | | | | | | | | | | |

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| --- | --- | --- | --- | --- | --- |
| MEDICATIONS TAKEN | | | | | |
| Is the subject currently or previously taking any medication including OTC, vitamins and/or | | | | | |
| supplements? | Yes |  | No |  |  |
| \*Record **all** medication on Concomitant Medications page | | | | | |

**VISIT 1 (SCREENING)**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| PREVIOUS MEDICAL HISTORY | | | | | | | | |
| **Is there any relevant medical history in the following systems?** | | | | | | | | |
| Code | System | \*Yes | No |  | Code | System | \*Yes | No |
| 1 | Cardiovascular |  |  |  | 9 | Neoplasia |  |  |
| 2 | Respiratory |  |  |  | 10 | Neurological |  |  |
| 3 | Hepato-biliary |  |  |  | 11 | Psychological |  |  |
| 4 | Gastro-intestinal |  |  |  | 12 | Immunological |  |  |
| 5 | Genito-urinary |  |  |  | 13 | Dermatological |  |  |
| 6 | Endocrine |  |  |  | 14 | Allergies |  |  |
| 7 | Haematological |  |  |  | 15 | Eyes, ear, nose, throat |  |  |
| 8 | Musculo-skeletal |  |  |  | 00 | Other |  |  |

\*If ***YES*** for any of the above, enter the code for each condition in the boxes below, give further details (including dates) and state if the condition is currently or potentially active. If giving details of surgery please specify the underlying cause. Use a separate line for each condition.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | Currently Active? | | |
| **Code** | **Details (including dates)** | | **Yes** | **No** |
|  |  | |  |  |
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| Signature: |  | Date: |  |  |  |  |  |  |  |  |  |
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**VISIT 1 (SCREENING)**

|  |  |  |  |
| --- | --- | --- | --- |
| PHYSICAL EXAMINATION (to be carried out by medical staff only) | | | |
| Code | System | \*Abnormal | Normal |
| 1 | General Appearance |  |  |
| 2 | Heart |  |  |
| 3 | Lungs |  |  |
| 4 | Abdomen |  |  |
| 5 | Extremities |  |  |
|  | | | |
| \* If ***ABNORMAL*** enter the code for each condition in the boxes below and give brief details. Please use a separate line for each condition. | | | |
|  | | | |
| Code | Details | | |
|  |  | | |
|  |  | | |
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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| VITAL SIGNS | | | | | | | | | | | | | |
| Pulse rate |  | |  | |  | | bpm | | | | | | |
|  | | | | | | | | | | | | | |
| Blood pressure (seated) | |  | |  | |  | | / |  |  |  | mmHg |  |
|  | | | | | | | | | | | | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ECG | | | | | | | |
| Is the ECG: | Normal | |  | Abnormal |  | **\*\*** | |
| \*\*Description*:* | | *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* | | | | | |
| Retain signed and dated trace in the plastic sleeve at back of CRF | | | | | | |  |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Signature: |  | Date: |  |  |  |  |  |  |  |  |  |
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**VISIT 1 (SCREENING)**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| LABORATORY ANALYSIS | | | | | | | | | |  | | | | | **Initials** |
|  | | | | | | | | | |  | | | | |  |
| Blood for haematology and biochemistry | | | | | | | | Taken by | | | | | | |  |
|  | | | | | | | | | | | | | | |
| **✓** | **Repeat Sample Required?** | **Date Taken (dd mmm yyyy)** | | | | | | | | | | | | |  |
|  | Haematology |  |  |  |  |  |  | |  | |  |  |  |  |  |
|  | Clinical Chemistry |  |  |  |  |  |  | |  | |  |  |  |  |  |
|  |  |  |  |  |  |  |  | |  | |  |  |  |  |  |

Please insert a copy of all results in the plastic sleeve at the back of the CRF.

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|  | | | | | | | | | | | | | |
| **Are all final results**: | | Normal |  | Abnormal NCS | |  | \*\*Abnormal CS | | | | |  | |
| \*\*Description*:* |  | | | | | | | | | | | | |
|  |  | | | | | | | | | | | | |
|  |  | | | | | | | | | | | | |
|  | | | | | | | | | | | | | |
| Does any result contradict study entry? | | | | | \*Yes | | |  | No | |  | |  |
|  | | | | | | | | | | | | | |
| Initials: | | | | | | | | | |  | | | |
|  | | | | | | | | | | | | | |
| \*If YES, subject must not continue. Please complete off study page. | | | | | | | | | | | | | |

|  |
| --- |
| Add Study Specific Data, as relevant for the particular study |

|  |  |  |  |  |  |  |  |  |  |  |  |
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| Signature: |  | Date: |  |  |  |  |  |  |  |  |  |
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**VISIT 1 (SCREENING)**

End of Visit Checklist: to be completed by Investigator

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Yes |  | No |
| 1 | Does the subject satisfy the inclusion and exclusion criteria to date? |  |  |  |
|  |  |  |  |  |
| 2 | Have all screening procedures been completed? |  |  |  |
|  |  |  |  |  |
| 3 | Has the concomitant medication page been completed? |  |  |  |
|  |  |  |  |  |
| 4 | Is the subject willing to proceed? |  |  |  |

Investigator

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |
| Is the subject to continue? |  |  |  |
|  | | | |
| Has medication been collected from Pharmacy? |  |  |  |
|  | | | |
| Have the dosing instructions been explained to the patient? |  |  |  |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Signature: |  | Date: |  |  |  |  |  |  |  |  |  |
|  |  |  | d | d | m | m | m | y | y | y | y |

|  |
| --- |
| If ‘**Yes**’ please: |
| Complete details of next visit and any other needed instructions on the instruction card. |
| Give the subject the instruction card |

**VISIT 2 (WEEK 1) Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**DD MMM YYYY**

|  |  |  |  |
| --- | --- | --- | --- |
| PHYSICAL EXAMINATION (to be carried out by medical staff only) | | | |
| Code | System | \*Abnormal | Normal |
| 1 | General Appearance |  |  |
| 2 | Heart |  |  |
| 3 | Lungs |  |  |
| 4 | Abdomen |  |  |
| 5 | Extremities |  |  |
|  | | | |
| **\* If any changes from baseline, complete adverse event page.** | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| VITAL SIGNS | | | | | | | | | | | | | |
| Pulse rate |  | |  | |  | | bpm | | | | | | |
|  | | | | | | | | | | | | | |
| Blood pressure (seated) | |  | |  | |  | | / |  |  |  | mmHg |  |
|  | | | | | | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| LABORATORY ANALYSIS | | | | | | | | | |  | | | | | **Initials** |
|  | | | | | | | | | |  | | | | |  |
| Blood for haematology and biochemistry | | | | | | | | Taken by | | | | | | |  |
|  | | | | | | | | | | | | | | |
| **✓** | **Repeat Sample Required?** | **Date Taken (dd mmm yyyy)** | | | | | | | | | | | | |  |
|  | Haematology |  |  |  |  |  |  | |  | |  |  |  |  |  |
|  | Clinical Chemistry |  |  |  |  |  |  | |  | |  |  |  |  |  |
|  |  |  |  |  |  |  |  | |  | |  |  |  |  |  |

Please insert a copy of all results in the plastic sleeve at the back of the CRF.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | | | | | |
| **Are all final results**: | | Normal |  | Abnormal NCS | |  | \*\*Abnormal CS | | | |  | |
| \*\*Description*:* |  | | | | | | | | | | | |
|  |  | | | | | | | | | | | |
|  | | | | | | | | | | | | |
| Does any result contradict continuation in the study? | | | | | \*Yes | | |  | No |  | |  |
|  | | | | | | | | | | | | |
| \*If YES, subject must not continue. Please complete off study page. | | | | | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Add Study Specific Data, as relevant for the particular study | | | | | | | | | | | |
| Signature: | |  | Date: |  |  |  |  |  |  |  |  |  |
|  | |  |  | d | d | m | m | m | y | y | y | y |

**VISIT 3 (WEEK 26) Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**DD MMM YYYY**

|  |  |  |  |
| --- | --- | --- | --- |
| PHYSICAL EXAMINATION (to be carried out by medical staff only) | | | |
| Code | System | \*Abnormal | Normal |
| 1 | General Appearance |  |  |
| 2 | Heart |  |  |
| 3 | Lungs |  |  |
| 4 | Abdomen |  |  |
| 5 | Extremities |  |  |
|  | | | |
| **\* If any changes from baseline, complete adverse event page.** | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| VITAL SIGNS | | | | | | | | | | | | | |
| Pulse rate |  | |  | |  | | bpm | | | | | | |
|  | | | | | | | | | | | | | |
| Blood pressure (seated) | |  | |  | |  | | / |  |  |  | mmHg |  |
|  | | | | | | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| LABORATORY ANALYSIS | | | | | | | | | |  | | | | | **Initials** |
|  | | | | | | | | | |  | | | | |  |
| Blood for haematology and biochemistry | | | | | | | | Taken by | | | | | | |  |
|  | | | | | | | | | | | | | | |
| **✓** | **Repeat Sample Required?** | **Date Taken (dd mmm yyyy)** | | | | | | | | | | | | |  |
|  | Haematology |  |  |  |  |  |  | |  | |  |  |  |  |  |
|  | Clinical Chemistry |  |  |  |  |  |  | |  | |  |  |  |  |  |
|  |  |  |  |  |  |  |  | |  | |  |  |  |  |  |

Please insert a copy of all results in the plastic sleeve at the back of the CRF.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | | | | | |
| **Are all final results**: | | Normal |  | Abnormal NCS | |  | \*\*Abnormal CS | | | |  | |
| \*\*Description*:* |  | | | | | | | | | | | |
|  |  | | | | | | | | | | | |
|  | | | | | | | | | | | | |
| Does any result contradict continuation in the study? | | | | | \*Yes | | |  | No |  | |  |
|  | | | | | | | | | | | | |
| \*If YES, subject must not continue. Please complete off study page. | | | | | | | | | | | | |

|  |
| --- |
| Add Study Specific Data, as relevant for the particular study |

|  |  |  |  |  |  |  |  |  |  |  |  |
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| Signature: |  | Date: |  |  |  |  |  |  |  |  |  |
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**VISIT 4 (WEEK 52) Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**DD MMM YYYY**

|  |  |  |  |
| --- | --- | --- | --- |
| PHYSICAL EXAMINATION (to be carried out by medical staff only) | | | |
| Code | System | \*Abnormal | Normal |
| 1 | General Appearance |  |  |
| 2 | Heart |  |  |
| 3 | Lungs |  |  |
| 4 | Abdomen |  |  |
| 5 | Extremities |  |  |
|  | | | |
| **\* If any changes from baseline, complete adverse event page.** | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| VITAL SIGNS | | | | | | | | | | | | | |
| Pulse rate |  | |  | |  | | bpm | | | | | | |
|  | | | | | | | | | | | | | |
| Blood pressure (seated) | |  | |  | |  | | / |  |  |  | mmHg |  |
|  | | | | | | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| LABORATORY ANALYSIS | | | | | | | | | |  | | | | | **Initials** |
|  | | | | | | | | | |  | | | | |  |
| Blood for haematology and biochemistry | | | | | | | | Taken by | | | | | | |  |
|  | | | | | | | | | | | | | | |
| **✓** | **Repeat Sample Required?** | **Date Taken (dd mmm yyyy)** | | | | | | | | | | | | |  |
|  | Haematology |  |  |  |  |  |  | |  | |  |  |  |  |  |
|  | Clinical Chemistry |  |  |  |  |  |  | |  | |  |  |  |  |  |
|  |  |  |  |  |  |  |  | |  | |  |  |  |  |  |

Please insert a copy of all results in the plastic sleeve at the back of the CRF.

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|  | | | | | | | | | | | | |
| **Are all final results**: | | Normal |  | Abnormal NCS | |  | \*\*Abnormal CS | | | |  | |
| \*\*Description*:* |  | | | | | | | | | | | |
|  |  | | | | | | | | | | | |
|  | | | | | | | | | | | | |
| Does any result contradict continuation in the study? | | | | | \*Yes | | |  | No |  | |  |
|  | | | | | | | | | | | | |
| \*If YES, subject must not continue. Please complete off study page. | | | | | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Add Study Specific Data, as relevant for the particular study | | | | | | | | | | | |
| Signature: | |  | Date: |  |  |  |  |  |  |  |  |  |
|  | |  |  | d | d | m | m | m | y | y | y | y |

**VISIT 5 (WEEK 56) Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**DD MMM YYYY**

|  |  |  |  |
| --- | --- | --- | --- |
| PHYSICAL EXAMINATION (to be carried out by medical staff only) | | | |
| Code | System | \*Abnormal | Normal |
| 1 | General Appearance |  |  |
| 2 | Heart |  |  |
| 3 | Lungs |  |  |
| 4 | Abdomen |  |  |
| 5 | Extremities |  |  |
|  | | | |
| **\* If any changes from baseline, complete adverse event page.** | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| VITAL SIGNS | | | | | | | | | | | | | |
| Pulse rate |  | |  | |  | | bpm | | | | | | |
|  | | | | | | | | | | | | | |
| Blood pressure (seated) | |  | |  | |  | | / |  |  |  | mmHg |  |
|  | | | | | | | | | | | | | |

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| LABORATORY ANALYSIS | | | | | | | | | |  | | | | | **Initials** |
|  | | | | | | | | | |  | | | | |  |
| Blood for U+Es | | | | | | | | Taken by | | | | | | |  |
|  | | | | | | | | | | | | | | |
| **✓** | **Repeat Sample Required?** | **Date Taken (dd mmm yyyy)** | | | | | | | | | | | | |  |
|  | Clinical Chemistry |  |  |  |  |  |  | |  | |  |  |  |  |  |
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Please insert a copy of all results in the plastic sleeve at the back of the CRF.

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|  | | | | | | | | | | | | |
| **Are all final results**: | | Normal |  | Abnormal NCS | |  | \*\*Abnormal CS | | | |  | |
| \*\*Description*:* |  | | | | | | | | | | | |
|  |  | | | | | | | | | | | |
|  | | | | | | | | | | | | |
| Has renal function remained stable? | | | | | Yes | | |  | \*No |  | |  |
|  | | | | | | | | | | | | |
| \*If No, record on adverse event page. | | | | | | | | | | | | |

|  |
| --- |
| Add Study Specific Data, as relevant for the particular study |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Signature: |  | Date: |  |  |  |  |  |  |  |  |  |
|  |  |  | d | d | m | m | m | y | y | y | y |

**CONCOMITANT MEDICATIONS**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Medication | Total Daily Dose | Units | Reason | Start Date  *(MM/DD/YYYY)* | Stop Date  *(MM/DD/YYYY)* | Continuing |
|  |  |  |  | \_\_\_ \_\_\_ / \_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_ \_\_\_ | \_\_\_ \_\_\_ / \_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_ \_\_\_ |  |
|  |  |  |  | \_\_\_ \_\_\_ / \_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_ \_\_\_ | \_\_\_ \_\_\_ / \_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_ \_\_\_ |  |
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| Adverse Events | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | |  | | | | | | | | | | | | | | |  | |  | | |
| Has the patient experienced any Adverse Events since signing the Informed Consent? | | | | | | | | | | | |  | Yes, specify below | | | | | | |  | | No | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | |
| **AE no.** | **Adverse Event** (diagnosis (if known) or signs/symptoms) | | **Start Date**  dd/mmm/yyyy  **and Time**  (24 hour clock) | **Stop Date**  dd/mmm/yyyy  **and Time**  (24 hour clock) | | **Outcome**  1=Recovered  2=Recovered with sequelae  3=Continuing  4=Patient Died  5=Change in AE  6=unknown | **Severity**  1=Mild  2=Moderate  3=Severe | **Plausible relationship to Study Drug** | | | **Action taken with Study Drug**  1=None  2=Dose Reduction Temporarily  3=Dose Reduced  4=Discontinued Temporarily  5=Discontinued | | | **Withdrawn due to AE?** | | | **Serious AE (SAE)?** | | | | **If SAE does it require immediate reporting? (see Protocol)?** | | | |
|  |  | |  |  | |  |  |  |  |  |  | | |  |  |  |  |  |  | |  | |  |  |
| / / | / / | |  |  | Yes |  |  | Yes |  |  | Yes | |  | |  | Yes |
|  |  | |  |  |  |  |  |  |  |  |  | |  | |  |  |
| **:** | **:** | |  |  | No |  |  | No |  |  | No | |  | |  | No |
|  |  | |  |  |  |  |  |  |  |  |  | |  | |  |  |
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| / / | / / | |  |  | Yes |  |  | Yes |  |  | Yes | |  | |  | Yes |
|  |  | |  |  |  |  |  |  |  |  |  | |  | |  |  |
| **:** | **:** | |  |  | No |  |  | No |  |  | No | |  | |  | No |
|  |  | |  |  |  |  |  |  |  |  |  | |  | |  |  |
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| / / | / / | |  |  | Yes |  |  | Yes |  |  | Yes | |  | |  | Yes |
|  |  | |  |  |  |  |  |  |  |  |  | |  | |  |  |
| **:** | **:** | |  |  | No |  |  | No |  |  | No | |  | |  | No |
|  |  | |  |  |  |  |  |  |  |  |  | |  | |  |  |

**OFF STUDY FORM**

|  |
| --- |
| Date Off Study: \_\_\_ \_\_\_ / \_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_ \_\_\_  *(MM/DD/YYYY)* |
| Date Last Study Medication Taken: \_\_\_ \_\_\_ / \_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_ \_\_\_  *(MM/DD/YYYY)* |

|  |
| --- |
| **Reason Off Study** (Please mark only the primary reason. Reasons **other than Completed Study** require explanation next to the response) |
| Completed study |
| AE/SAE **(complete AE CRF & SAE form, if applicable) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| Lost to follow-up \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Non-compliant participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Concomitant medication \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Medical contraindication \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Withdraw consent \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Death **(complete SAE form) \_\_**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |