NCI, DIVISION OF CANCER PREVENTION (DCP) SERIOUS ADVERSE EVENT REPORT FORM

**REQUIRED FIELDS ON ALL REPORTS (Note: All SAEs must also be reported on the AE CRF)**

|  |  |  |
| --- | --- | --- |
| Today's Date: | Sponsor: NCI, DCP | Study (Indication): |
| Enter Date |  |
| Drug(s) under Investigation: | IND No.: | Study (Indication) |
| Enter Drug(s) | Enter IND No. |  |

1. **Study Subject Information**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Study Participant # or PID #  Enter PID | 2. Year of Birth: Enter YOB | 3. Weight at Time of Event: | 4. Height at Time of Event: |
| Enter Weight | Enter Height. |
| [☐] kg [☐] lbs. [☐] not available | [☐] cm [☐] in [☐] not available |
| Sex: (choose one) [☐] M[☐] F | | Race:  Choose an item. | Ethnicity: Choose an item. |

1. **Event Information**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| [☐] Initial Event Report [☐] Follow-up Report Follow-up No. | | | | |
| Event Onset Date: Date (Month/Day/Year) | | Primary Event (diagnosis): Primary Event. | | |
| Event Approx. Time: Time (Indicate A.M./P.M.) | |
| Event Occurred at: Event Occurred At | |
| Duration of Drug Exposure at Event: Enter Duration of Exposure | | Primary Treatment Approx. Time (A.M./P.M.): Treat Time | | |
| Primary Treatment of Event: Primary Treatment | | |
| Attending Physician (Name): Enter Attending Physician Name | | | | |
| Phone/FAX No.: Enter Attending Physician Phone/FAX | | | | |
| Hospital/Clinic: Enter Hospital/Clinic Name | | | | |
| Address: | Hospital/Clinic Address |  |  |  |
| Describe Event (if applicable, include dates of hospitalization for event): Describe Event | | | | |
| Form Completed By: (Print Name) Print Name | | | Title Title |  |
| Investigator Signature | |  | Date | Phone No.Phone No. |

**ALL FIELDS APPEARING IN THE FOLLOWING PAGES (C-F) MUST BE COMPLETED FOR THE INITIAL REPORT; THEREAFTER, FILL IN ONLY SECTIONS THAT PROVIDE ADDITIONAL/ CORRECTIVE INFORMATION.**

1. **Site Information**

|  |  |
| --- | --- |
| 1. Investigator Name Enter Investigator Name | |
| 2. Address | Enter Site Address |

1. **Suspect Medication(s)**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 1. Study Design: [☐] Blind [☐] Open/Unblind | | | | | | | |
| Possible Dose (*e.g.,* 300 mg) Dose | | Frequency (*e.g.,* qd) Freq | | | Route (*e.g.*, po) Route | | |
| 2. Study Drug Enter Study Drug |  |  |  | Formulation (*e.g.,* tablet, solution) Enter Study Drug Formulation | |  |  |
|  |  |  |  | Lot No. (If known)  Enter Study Drug Lot Number | |  |  |
| 3. Start Date of Study Drug (Month/Day/Year): Start Date Study Drug | | | | | | | |
| 4. Was blind broken due to event? [☐] No [☐] Yes [☐] NA | | | | | | | |
| 5. Was Study Drug stopped/interrupted/reduced in response to event? [☐] No [☐] Yes  >> If yes, complete a-e: | | | | | | | |
| a. If stopped, specify date study drug last taken: Date Last Taken (Month/Day/Year) | | | | | | [☐] NA |  |
| b. If reduced, specify: New dose New Dose | | | Date reduced Date Reduced (Month/Day/Year) | | | [☐] NA |  |
| c. If interrupted, specify total number of days not given: Total Days Drug Not Given | | | | | | [☐] NA |  |
| d. Did event abate after study drug was stopped or dose reduced? [☐] NA [☐] Yes [☐] No  e. Did event reappear after study drug was reintroduced? [☐] NA [☐] Yes [☐] No | | | | | |  |  |
| 6. Was patient taking any other medications concomitantly at the time of the event? [☐] No [☐] Yes >> If Yes, complete below.  **(DO NOT LIST DRUGS USED TO TREAT EVENT)** | | | | | | | |
| **Drug Name** | **Dose Units** | **Dose Frequency** | **Route** | **Indication for Use** | **Start Date** (MM/DD/YYYY) | **Stop Date**  (MM/DD/YYYY) | **or mark (X) if continuing** |
| Drug Name | Units | Frequency | Route | Indication | Start Date | Stop Date | ☐ |
| Drug Name | Units | Frequency | Route | Indication | Start Date | Stop Date | ☐ |
| Drug Name | Units | Frequency | Route | Indication | Start Date | Stop Date | ☐ |
| Drug Name | Units | Frequency | Route | Indication | Start Date | Stop Date | ☐ |
| Drug Name | Units | Frequency | Route | Indication | Start Date | Stop Date | ☐ |
| Drug Name | Units | Frequency | Route | Indication | Start Date | Stop Date | ☐ |

(continue in section G. Continued Information if necessary)

1. **Adverse Event**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1. Relevant Laboratory/Diagnostic Tests No tests performed [☐] | | | | | | |
| Date | Month | Day | Year | Test Test | Results Results |  |
|  | Month | Day | Year |  | Actual Value Actual Value | Normal Range Range |
| Date | Month | Day | Year | Test Test | Results Results |  |
|  | Month | Day | Year |  | Actual Value Actual Value | Normal Range Range |
| Date | Month | Day | Year | Test Test | Results Results |  |
|  | Month | Day | Year |  | Actual Value Actual Value | Normal Range Range |

(continue in section G. Continued Information if necessary)

|  |  |  |
| --- | --- | --- |
| 2. Relevant Medical History, including pre-existing conditions (*e.g.,* allergies, pregnancy, smoking & alcohol use, hepatic/renal dysfunction, medical/surgical history, *etc.*) | | |
| Date (if known) Date | Diseases/Surgeries/Treatment | Disease/Surgery/Treatment |
| Date (if known) Date | Diseases/Surgeries/Treatment | Disease/Surgery/Treatment |
| Date (if known) Date | Diseases/Surgeries/Treatment | Disease/Surgery/Treatment |

(continue in section G. Continued Information if necessary)

|  |  |  |
| --- | --- | --- |
| 3. CTCAE Term CTCAE Term | CTCAE version # Version | NA [☐] |
| Grade [☐] 1 [☐] 2 [☐] 3 [☐] 4 [☐] 5 |  |  |
| 4. Why Serious?  [☐] Results in death [☐] Is life-threatening [☐] Requires inpatient hospitalization or prolongation of existing hospitalization  [☐] Results in persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions  [☐] Is a congenital anomaly/birth defect | | |
| [☐] Important medical event, specify: |  |  |
| 5. Outcome of Event (at time of report)  [☐] Resolved **–** date ((Month/Day/Year): Enter Date | [☐] Improved [☐] Unchanged [☐] Worse [☐] Not available | |
| [☐] Fatal **-** date of death (Month/Day/Year): Enter Date | Autopsy Performed? [☐] Y [☐] N [☐] NA (choose one) | |
| Cause of Death:Cause of death (please attach death certificate and autopsy report, if applicable) | | |
| 6. Investigator's opinion of the relationship between the event and the study drug. Check applicable box: | | |
| [☐] Unrelated [☐] Unlikely [☐] Possible [☐] Probable [☐] Definite | | |
| 7. Was this event reported by the Investigator to (check all that apply): [☐] IRB/CIRB [☐] Other Investigators | | |
| participating in this study; if checked, please list names and institutions | | |

1. **Comments/Clarifications:**

|  |  |  |
| --- | --- | --- |
| **FOR NCI USE ONLY** | | |
| 1. Date NCI notified of event (Month/Day/Year): Date NCI Notified | | |
| 2. Medical Monitor Review:  Medical Assessment of Event (including drug relationship and expectedness): Medical Assessment | | |
| Medical Monitor’s opinion of seriousness:  [☐] Results in death [☐] Is life-threatening  [☐] Requires inpatient hospitalization or prolongation of existing hospitalization  [☐] Results in persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions  [☐] Is a congenital anomaly/birth defect | | |
| [☐] Important medical event, specify: |  |  |
| Important Medical Event Specify |  |  |
| [☐] Not serious, specify: Not serious, specify |  |  |
| Medical Monitor’s opinion of expectedness (based on Investigator’s Brochure or other information provided to the site):  [☐] Expected [☐] Unexpected  Medical Monitor's opinion of the relationship between the event and the study drug. Check applicable box: [☐] Unrelated [☐] Unlikely [☐] Possible [☐] Probable [☐] Definite  Is this an FDA reportable (7 calendar days) event? [☐] Yes [☐] No  Is this an FDA reportable (15 calendar days) event? [☐] Yes [☐] No | | |
| >> If No, specify reason: Not FDA Reportable Reason  >> If Yes, the event is considered an unanticipated problem (21 CFR §312.66). Specify any corrective actions to be taken by the investigator: Corrective actions, specify | | |
| Is more information expected? [☐] Yes [☐] No | | |
| >> If Yes, specify: More information, specify |  |  |
| Medical Monitor: Print name Name | Signature | Date |

1. **Continued Information**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Was patient taking any other medications concomitantly at the time of the event? (continued from page 2)  **(DO NOT LIST DRUGS USED TO TREAT EVENT)** | | | | | | | | | | | |
| **Drug Name** | | | **Dose Units** | **Dose Frequency** | | **Route** | **Indication for Use** | **Start Date** (MM/DD/ YYYY) | **Stop Date**  (MM/DD/YYYY) | **or  mark (X) if continuing** | |
| Drug Name | | | Units | Frequency | | Route | Indication | Start Date | Stop Date | | ☐ |
| Drug Name | | | Units | Frequency | | Route | Indication | Start Date | Stop Date | | ☐ |
| Drug Name | | | Units | Frequency | | Route | Indication | Start Date | Stop Date | | ☐ |
| Drug Name | | | Units | Frequency | | Route | Indication | Start Date | Stop Date | | ☐ |
| Drug Name | | | Units | Frequency | | Route | Indication | Start Date | Stop Date | | ☐ |
| Drug Name | | | Units | Frequency | | Route | Indication | Start Date | Stop Date | | ☐ |
| Drug Name | | | Units | Frequency | | Route | Indication | Start Date | Stop Date | | ☐ |
| Drug Name | | | Units | Frequency | | Route | Indication | Start Date | Stop Date | | ☐ |
| Drug Name | | | Units | Frequency | | Route | Indication | Start Date | Stop Date | | ☐ |
| Drug Name | | | Units | Frequency | | Route | Indication | Start Date | Stop Date | | ☐ |
| Drug Name | | | Month | Frequency | | Route | Indication | Start Date | Stop Date | | ☐ |
| Relevant Laboratory/Diagnostic Tests (continued from page 3) | | | | | | | | | | | |  |
| Date | Month | Day | Year | | Test Test | Results Lab Results | |  |  | |  |
|  | Month | Day | Year | |  | Actual Value Actual Value | | Normal Range Normal | | | |
| Date | Month | Day | Year | | Test Test | Results Lab Results | |  |  | |  |
|  | Month | Day | Year | |  | Actual Value Actual Value | | Normal Range Normal | | | |
| Date | Month | Day | Year | | Test Test | Results Lab Results | |  |  | |  |
|  | Month | Day | Year | |  | Actual Value Actual Value | | Normal Range Normal | | | |
| Date | Month | Day | Year | | Test Test | Results Lab Results | |  |  | |  |
|  | Month | Day | Year | |  | Actual Value Actual Value | | Normal Range Normal | | | |
| Date | Month | Day | Year | | Test Test | Results Lab Results | |  |  | |  |
|  | Month | Day | Year | |  | Actual Value Actual Value | | Normal Range Normal | | | |
| Date | Month | Day | Year | | Test Test | Results Lab Results | |  |  | |  |
|  | Month | Day | Year | |  | Actual Value Actual Value | | Normal Range Normal | | | |
| Date | Month | Day | Year | | Test Test | Results Lab Results | |  |  | |  |
|  | Month | Day | Year | |  | Actual Value Actual Value | | Normal Range Normal | | | |
| Date | Month | Day | Year | | Test Test | Results Lab Results | |  |  | |  |
|  | Month | Day |  | |  | Actual Value Actual Value | | Normal Range Normal | | | |

|  |  |
| --- | --- |
| Relevant Laboratory/Diagnostic Tests (continued from page 3) | |
| Relevant Medical History, including pre-existing conditions (e.g., allergies, pregnancy, smoking & alcohol use, hepatic/renal dysfunction, medical/surgical history, etc.) (continued from page 3) | |
| Date (if known) Date | Diseases/Surgeries/Treatment Diseases/Surgeries/Treatment |
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