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. |  |

# A. 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 |
| Gender: (choose one) [] M[] F | | Race:  Choose an item. | Ethnicity:  Choose an item. |

# B. 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 | | Investigator signature line | | 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.**

# C. Site Information

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

# D. 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** | | | **Route** | | **Indication for Use** | **Start Date**  (MM/DD/YYYY) | **Stop Date** (MM/DD/YYYY)  **or mark (X) if continuing** | |
| Units | Frequency | |
| 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)

# E. 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 | | | | |

# F. 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 | Medical Monitor Signature Line | Date |

# G. Continued Information

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 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** | | **Route** | **Indication for Use** | **Start Date** (MM/DD/YYYY) | **Stop Date** (MM/DD/YYYY) **or mark (X) if continuing** | |
| Units | Frequency |
| 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 | Units | 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 | Year | |  | Actual Value Actual Value | Normal Range Normal |
| 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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