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 DrugEnter 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 [[ ] ] Noe. 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 [[ ] ] UnexpectedMedical Monitor's opinion of the relationship between the event and the study drug. Check applicable box:[[ ] ] Unrelated [[ ] ] Unlikely [[ ] ] Possible [[ ] ] Probable [[ ] ] DefiniteIs this an FDA reportable (7 calendar days) event? [[ ] ] Yes [[ ] ] NoIs 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

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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** | **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 |
| Date (if known) Date | Diseases/Surgeries/Treatment Diseases/Surgeries/Treatment |
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