|  |
| --- |
| **Adverse Event Form** |

|  |  |
| --- | --- |
| Study title | |
| Participant ID | Protocol Version No |
| Principal investigator | Study site |

**Treatment group < insert treatment group >**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Adverse event | Body system code \* | Date of onset  dd/mm/yyyyy | Relationship with study interventions  Drug/device /procedure \* | Action taken with study drugs /interventions  1 none  2 Discontinued permanently  3 discontinued temporarily  4 dose decreased  5 dose increased  6 doses delayed  Other specify\_\_\_\_ | Serious adverse event \*  0 No  1 Yes | Expected  0 unexpected  1 expected | Date of resolution dd/mm/yyyy | Unanticipated  Problem (UP)\*  0 No  1 Yes | Event status  1 recovered without treatment  2 recovered with treatment  3 still present no treatment  4still present being treated  5 under observation and monitoring  6 death | PI signature |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

|  |  |  |
| --- | --- | --- |
| Body system code | | |
| 01Respiratory  02 Digestive system and abdomen  03 Dermatological  04 Speech and voice  05 Ear nose and throat | 06 Cardiovascular  07 Nervous system  08 Musculoskeletal system  09 Genitourinary  10 Eye  11 Endocrine /metabolic | 12 Cognition, perception emotional status behavior  13 Respiratory  14 Others specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

|  |
| --- |
| **Grade**  Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0 Published: November 27, 2017 U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES National Institutes of Health National Cancer Institute  **Grade 1** Mild: asymptomatic or mild symptoms; clinical or diagnostic observations only; interventions not indicated usually  **Grade 2** Moderate; minimal local or noninvasive intervention indicated, limiting age appropriate instrumental ADL\*  **Grade 3** severe or medically significant but not immediately life threatening, hospitalization or prolongation of hospitalization indicated; disabling limiting self-care ADL\*  **Grade 4** life threatening consequences; urgent intervention indicated  Grade 5 death related to adverse event  Activities of Daily Living (ADL)  Instrumental ADL refer to preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.  Self -care ADL refer to bathing, dressing and undressing, feeding self, using the toilet, taking medications, and not bedridden  **Relationship with the study interventions**  I **certain:** clear study drugs/interventions link with timing, withdrawal and no other cause  2 **probable/ likely:** likely related with study drugs/interventions with reasonable time relationship, unlikely due to other conditions  3 **possible: Event** or lab abnormality with reasonable time relationship with study interventions, but also could be explained by disease or other drugs  4 **unlikely:** relationship with study interventions improbable but not impossible, disease or other drugs provide plausible explanation  5 **conditional / classified:** More data needed for proper assessment, additional data under examination  6 **unassessable / unclassified** report suggest adverse reaction, cannot be judged because information is insufficient or contradictory, data cannot be supplemented or verified  **Serious adverse event**: if serious adverse event, complete serious adverse event forms and follow reporting guidelines  **Unanticipated problem (UP):** if unanticipated problem complete UP form |