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|  **Adverse Event Form**  |

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

**Treatment group < insert treatment group >**

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| **Adverse event**  | **Body system code \*** | **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 Dose delayed 7 Other specify\_\_\_\_  | **Grade of severity** \* | **Expected**0 unexpected 1 expected  |  **Date**  dd/mm/yyyy | **Unanticipated** **Problem (UP)\***0 No1 Yes | **Event status** 1 recovered without treatment 2 recovered with treatment3 still present no treatment 4still present being treated5 under observation and monitoring6 death  | **PI signature**  |
| onset | Resolution  |
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| Body system code  |
| 01Respiratory 02 Digestive system and abdomen03 Dermatological 04 Speech and voice05 Ear nose and throat  | 06 Cardiovascular 07 Nervous system08 Musculoskeletal system09 Genitourinary 10 Eye 11 Endocrine /metabolic  | 12 Cognition, perception emotional status behavior13 Respiratory 14 Others specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **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 conditions3 **possible: Event** or lab abnormality with reasonable time relationship with study interventions, but also could be explained by disease or other drugs4 **unlikely:** relationship with study interventions improbable but not impossible, disease or other drugs provide plausible explanation5 **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 |